

EXHIBIT B37

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE EASTERN DISTRICT OF NEW JERSEY
3 - - -
4

5 IN RE: JOHNSON & :
6 JOHNSON TALCUM POWDER :
7 PRODUCTS MARKETING, :
8 SALES PRACTICES, AND : NO. 16-2738
9 PRODUCTS LIABILITY : (FLW) (LHG)
10 LITIGATION :
11 THIS DOCUMENT RELATES :
12 TO ALL CASES :
13

14 - - -
15 January 4, 2019
16 - - -
17

18 Videotaped deposition of Michael
19 Crowley, Ph.D., produced as a witness at the
20 instance of the Defendant, Johnson & Johnson
21 entities, and duly sworn, was taken in the
22 above-styled and numbered cause on the 4th
23 day of January, 2019, from 9:07 a.m. to
24 5:59 p.m., before Steven Stogel, CSR in and
for the State of Texas and Certified LiveNote
Reporter, reported by machine shorthand the
Hilton Austin Hotel, 500 East 4th Street,
Austin, Texas, pursuant to the Federal Rules
of Civil Procedure and the provisions stated
on the record or attached hereto.

25 - - -
26
27 GOLKOW LITIGATION SERVICES
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30

Michael Crowley, Ph.D.

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1	---		
2	THE VIDEOGRAPHER: Here begins		
3	the deposition of Dr. Michael Crowley.		
4	Today's date is January 4th, 2019. The		
5	time is 9:07 a.m.		
6	Will the court reporter please		
7	swear in the witness?		
8	(Witness sworn)		
9	MR. ZELLERS: At the outset, the		
10	Johnson & Johnson defendants make an		
11	objection to anyone attending this		
12	deposition remotely as the deposition		
13	protocol order does not provide for		
14	remote attendance. We can begin.		
15	MICHAEL CROWLEY, Ph.D.,		
16	having been first duly sworn, testified as		
17	follows:		
18	---		
19	EXAMINATION		
20	---		
21	BY MR. ZELLERS:		
22	Q. Can you state your name, please?		
23	A. Michael Crowley.		
24	Q. Dr. Crowley, you are here to		

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<p>1 provide a deposition as an expert witness on 2 behalf of the plaintiffs. Is that right? 3 A. Yes. 4 Q. You've given deposition 5 testimony in the past? 6 A. Yes. 7 Q. On how many occasions? 8 A. I believe four. 9 Q. What types of cases were those? 10 A. Patent disputes and one contract 11 dispute. 12 Q. You are familiar with the 13 general rules we're going to follow. 14 Correct? 15 A. Yes. 16 Q. If at any time I ask you a 17 question or any of the counsel ask you a 18 question that you don't understand, please 19 don't answer it. Tell us you don't 20 understand, and I will repeat or rephrase the 21 question so it is clear to you. Can you do 22 that? 23 A. Yes. 24 Q. If you answer a question, then</p>	<p>Page 10</p> <p>1 Is that correct? 2 A. That's correct. 3 Q. At some point today on a break, 4 if you could just read through the document 5 request and the notice of deposition, because 6 I'd like to ask you the question, "Have you 7 produced all responsive documents?" Can you 8 do that at some point today? 9 A. Yes. 10 Q. You have in front of you your 11 computer. For what purpose do you have your 12 computer open today? 13 A. My report and the materials that 14 I viewed generating that report on it. 15 Q. Anything else on the computer 16 that you have with you here today -- 17 A. Well, yes. 18 Q. -- that's pertinent to this 19 deposition? 20 A. I don't think so. I mean, I 21 have scientific information on there that I 22 use in the normal course of doing my business 23 that are on the computer. 24 Q. Prior to the start of the</p>
<p>1 we will assume that you understood it. Is 2 that fair? 3 A. Yes. 4 Q. You are here today pursuant to a 5 notice of deposition. Is that right? 6 A. I was never given a notice. 7 Q. Let me provide you with a notice 8 of deposition, which we'll mark as Deposition 9 Exhibit 1. 10 (Exhibit No. 1 marked) 11 MS. O'DELL: We'll just add that 12 objections to the notice have been -- 13 objections have been served to certain 14 document requests that have been issued 15 in the notice, so I would just reassert 16 those objections at this point. 17 Prior to the beginning of the 18 deposition, I provided materials in 19 response to the document request that 20 plaintiffs deem non-objectionable, so 21 just so the record is clear on that. 22 BY MR. ZELLERS: 23 Q. Dr. Crowley, you have not seen 24 the notice of deposition, Exhibit 1, before.</p>	<p>Page 11</p> <p>1 deposition, Counsel for the plaintiffs 2 produced to us certain documents. I will 3 mark those. 4 (Exhibit No. 2 marked) 5 BY MR. ZELLERS: 6 Q. First is a series of invoices. 7 We'll mark your invoices as Deposition 8 Exhibit 2. 9 Just quickly going through the 10 invoices, it appears that the initial 11 invoice -- or at least the top invoice is for 12 Wednesday, May 30th, 2018. 13 Is that around the time that you 14 were retained in this matter? 15 A. I believe so. 16 Q. The invoices are addressed to 17 Ms. O'Dell at the Beasley Allen firm. Is 18 that the firm that has retained you with 19 respect to the work you've done in the talk 20 MDL? 21 A. Yes. 22 Q. The first page of Exhibit 2 is 23 Invoice 8015. We have Invoice 800 -- strike 24 that -- 8022, Invoice 8027, Invoice 8035,</p>

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<p>1 Invoice 8041, Invoice 8043, with the last 2 time entry on Invoice 8043 being October of 3 2018. 4 Are these all of the invoices 5 that you have generated in the talc MDL 6 matter? 7 A. No. 8 Q. What additional invoices have 9 you generated in the talc MDL matter? 10 A. Since that time, I've done some 11 more work in preparing the document, my 12 report, that I haven't submitted yet. I'll 13 submit an invoice for appearing here today. 14 MS. O'DELL: I think there was 15 some confusion there. 16 MR. ZELLERS: I'll clear it up. 17 BY MR. ZELLERS: 18 Q. It appears that you are a 19 regular biller in that each of the invoices 20 are done at the end of each month. Is that 21 your typical billing practice? 22 A. Yes. 23 Q. So we have invoices that are 24 generated on a monthly basis through the</p>	<p>Page 14</p> <p>1 Q. -- of 2019? 2 A. No. 3 Q. The last invoice -- 4 A. I'd have to go check when my 5 last invoice was. We sent the report in in 6 November, I think, so it was probably at the 7 end of November. 8 Q. What I would like to do is to 9 come back to this set of questions after the 10 break. 11 MR. ZELLERS: And, Ms. O'Dell, 12 if you could just check to see if there 13 are additional invoices. 14 BY MR. ZELLERS: 15 Q. What is your recollection of the 16 amount of time that you've spent on this 17 matter, the talc MDL matter, during the month 18 of November? 19 A. I have no recollection. I'd 20 have to go check the document. 21 Q. Are you able to give me an 22 estimate? 23 A. Well, I'll pull up the document 24 if you'd like.</p>
<p>1 invoices that -- or invoice that was 2 generated on November 1st of 2018. Is that 3 right? 4 A. Yes. 5 Q. Did you generate an invoice on 6 December 1st of 2018? 7 A. I believe I have, yeah. 8 Q. Do you have that here with you 9 today? 10 A. I have it on my computer. 11 Q. All right. You can print it here today? 12 A. I believe so. I don't have access to a printer, but if you can get me access to a printer, I'll print it. 13 MS. O'DELL: I thought we had all the invoices in the stack I gave you. I will endeavor at a break to get the second -- the last invoice. Just an oversight. 14 BY MR. ZELLERS: 15 Q. Dr. Crowley, did you issue an invoice on or about January 1st or 2nd -- 16 A. No.</p>	<p>Page 15</p> <p>1 Q. My question is: Can you give us 2 an estimate? 3 A. I'd prefer not. I'd prefer just 4 to look at my invoice and tell you what it 5 says. 6 Q. Can you give us an estimate as 7 to the amount of time that you spent in 8 December of 2018 relating to the talc MDL 9 matter? 10 A. (No audible response) 11 Q. You're pulling something up on 12 your computer. Is that correct? 13 A. Uh-huh. 14 Q. Okay. Do you need to do that in 15 order to try to answer that question? 16 A. I do. I don't recall -- I don't 17 think there were many hours in December. 18 MS. O'DELL: Just testify to 19 your recollection, Dr. Crowley, and to 20 the degree there's been an invoice 21 produced -- or given to us that I 22 haven't produced, as I mentioned to 23 Counsel, that's an oversight. It was 24 not intentional. I'll get that to you.</p>

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<p>1 But to the degree you have a 2 memory or an estimate of hours, that's 3 fine. Just give an estimate. 4 A. Yeah. I think in December it 5 was less than ten hours. 6 BY MR. ZELLERS: 7 Q. Do you have an estimate for 8 November? 9 A. I really -- I mean, I don't. 10 Q. How much time have you spent 11 during the first few days of this year, 2019, 12 in preparation for the deposition here today? 13 A. Less than ten. 14 Q. The next document that you 15 brought with you today -- or that has been 16 produced by counsel for the plaintiffs 17 appears to be a supplement to your report. 18 We will mark that as Deposition Exhibit 3. 19 (Exhibit No. 3 marked) 20 BY MR. ZELLERS: 21 Q. Deposition Exhibit 3 consists 22 of -- it appears to be nine pages of 23 information. The first page at the top has 24 got a fragrance chemical description. The</p> <p style="text-align: right;">Page 18</p>	<p>1 A. No changes to my opinions. 2 Q. When did you prepare Deposition 3 Exhibit 3? 4 A. It was before Christmas, I 5 believe. 6 Q. Can you be any more precise than 7 that? 8 A. Yes. I'll tell you the date. 9 Q. Well, again, we don't want you 10 to make this an exercise where you try to 11 look up each answer. If you have a rough -- 12 A. I finished it on December 18th. 13 Q. Thank you. Have you made any 14 other changes or updates to your report? 15 A. No. 16 Q. You said that information was 17 provided to you shortly before you produced 18 your report. Is that right? 19 A. Yes. 20 Q. My recollection is that you 21 produced a report in this matter and then a 22 week or two later you produced an updated 23 report. Is that right? 24 A. No.</p> <p style="text-align: right;">Page 20</p>
<p>1 next column, J&J CAS number. The next 2 column, Crowley CAS number, and then 3 comments. 4 Can you tell us what Exhibit 3 5 is? 6 A. Yes. I think two or three days 7 prior to submission of my expert report, we 8 were provided with a document from J&J that 9 disclosed the chemical abstract service 10 numbers for all of the fragrance chemicals. 11 When I initiated work on this, I didn't have 12 CAS numbers, so I had to identify them for 13 the chemicals as I had been given them. 14 So this document is a 15 cross-reference that compares the CAS numbers 16 provided by J&J to those that I identified 17 for the fragrance chemicals and describes if 18 there is a difference -- what these differences are 19 and if it has any bearing on the data in my 20 report. 21 Q. How, if at all, does the 22 information contained in Deposition Exhibit 3 23 change or alter any of the opinions that 24 you're offering in this matter?</p> <p style="text-align: right;">Page 19</p>	<p>1 MS. O'DELL: No. Object to the 2 form. 3 MR. ZELLERS: All right. I'll 4 ask some specific questions when I get 5 to that. 6 BY MR. ZELLERS: 7 Q. Your recollection is you have 8 only produced one report -- 9 A. That's -- 10 Q. -- in this matter? 11 A. That's correct. 12 Q. The next item that was produced 13 today in connection with your deposition by 14 counsel for plaintiffs is Deposition 15 Exhibit 4. 16 (Exhibit No. 4 marked) 17 BY MR. ZELLERS: 18 Q. It appears to be an -- well, the 19 title of Deposition Exhibit 4 is "Guidance 20 for Industry Nonclinical Studies for the 21 Safety Evaluation of Pharmaceutical 22 Excipients." 23 What is Deposition Exhibit 4? 24 A. This is an FDA guidance document</p> <p style="text-align: right;">Page 21</p>

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<p>1 describing how pharmaceutical excipients 2 are -- inactive ingredients are to be 3 examined for safety. 4 Q. For what purpose did you bring 5 Deposition Exhibit 4 today? 6 A. This represents the FDA's 7 current thinking on how to examine inactive 8 ingredients for safety. 9 Q. What's the date of -- 10 A. This was issued in May of 2005. 11 Q. That is the most up-to-date 12 guidance document from the FDA. Is that 13 right? 14 A. I believe so. 15 Q. Do you believe that that 16 document applies to fragrance chemicals that 17 you're talking about here today? 18 A. Yes. 19 Q. Deposition Exhibit No. 5 is a 20 textbook. 21 MR. ZELLERS: We'll make 22 arrangements or figure out how to make 23 this a part of the record. 24 (Exhibit No. 5 marked)</p>	<p>Page 22</p> <p>1 or information is contained on Exhibit 6? 2 A. This has my expert report and 3 the underlying data upon which I relied to 4 generate that report. 5 Is it okay if I go ahead and 6 plug it in, or is that for you? 7 Q. Do you need to plug it in, or is 8 it already on your computer? 9 A. It's already there. 10 Q. No. Put that aside, and we'll 11 have the court reporter make a copy of that, 12 and that will be a part of this record. 13 Is there anything new or 14 additional on the thumb drive which we have 15 marked as Exhibit 6 that has either not been 16 produced here today or was a part of your 17 report? 18 A. I don't believe so. 19 MS. O'DELL: No. I can just say 20 that because I prepared the jump drive. 21 I think it might be just quicker 22 to use the jump drive to pull up 23 documents because of the internet 24 access in this room. So I'll just make</p>
<p>1 BY MR. ZELLERS: 2 Q. But it's titled "Excipient 3 Toxicity and Safety," edited by Myra Weiner 4 and Lois Kotkoskie, Volume 103. 5 A. Marcel Dekker is the publisher. 6 Q. It appears to be a 2007 7 publication. Can you tell us generally what 8 Exhibit 5 is? 9 A. It's a book describing how 10 toxicity and safety studies are to be 11 conducted for inactive ingredients. 12 Q. For what purpose have you 13 brought with you Exhibit 5 today? 14 A. For reference. 15 Q. Finally, you have brought with 16 you -- or has been produced through counsel 17 for plaintiffs a thumb drive, which we will 18 mark as Deposition Exhibit 6. 19 (Exhibit No. 6 marked)</p> <p>20 BY MR. ZELLERS: 21 Q. Are you familiar with Deposition 22 Exhibit 6? 23 A. Yes. 24 Q. Can you tell us what documents</p>	<p>Page 23</p> <p>1 that as an observation. If you don't 2 have any objection to him using the 3 jump drive -- you're welcome to -- to 4 look at it in advance, but -- 5 BY MR. ZELLERS: 6 Q. Dr. Crowley, if, as we go along, 7 you need to make reference to the jump drive, 8 you know, please do. Tell us that you're 9 going to be making a reference to it so we're 10 all aware as to what you're doing and what 11 documents you are reviewing. 12 I do intend to give you hard 13 copies of the documents that I have questions 14 about, but if you need to plug in the jump 15 drive and refer to it, it's okay with me, as 16 long as you state on the record what it is 17 you're doing. 18 A. Okay. 19 Q. Your report in this matter we 20 will mark as Deposition Exhibit 7. 21 (Exhibit No. 7 marked)</p> <p>22 BY MR. ZELLERS: 23 Q. Can you review Deposition 24 Exhibit 7 and tell us if that is your report?</p>

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<p>1 caption at the top is "References." 2 Can you look at Deposition 3 Exhibit 9 and tell us what that is? 4 A. This appears to be the reference 5 section from my report. 6 Q. What -- strike that. 7 How do you use the term 8 "reference"? What do you mean by "reference" 9 when you put that -- 10 A. These are items that I cited 11 within the report. 12 MS. O'DELL: Do you need me to 13 give something back? 14 MR. ZELLERS: No. But this will 15 be 10 as well as what I'm handing to 16 you. 17 MS. O'DELL: Okay. 18 MR. ZELLERS: The witness just 19 has 9 right now, which is the first 20 document. 21 MS. O'DELL: Okay. 22 BY MR. ZELLERS: 23 Q. References to you, in which 24 you're referring to, are the materials that</p> <p>1 you cite to in your report. Is that right? 2 A. In the body of the report, 3 that's correct. There were more things that 4 I cited in the appendices. 5 Q. Are the appendices a part of 6 your report? 7 A. Yes. 8 Q. The references, what we have 9 marked as Exhibit 9, is that a complete 10 listing of all the citations in your report, 11 including appendices? 12 A. No. 13 MS. O'DELL: Object to form. 14 A. Yeah. No. There were reports 15 from the literature, internet links within 16 the appendices that do not appear in 17 Section 7 of my report. 18 BY MR. ZELLERS: 19 Q. In order, then, for counsel in 20 this case to understand what is cited in your 21 report, we need to look at the body of the 22 report and take a look at the list of 23 references. Is that correct? 24 A. You need to look at the entire</p>	<p>Page 26</p> <p>Page 28</p>
<p>1 report, the body of the report and the 2 appendices. 3 Q. Did you prepare the reference 4 list? 5 A. I did. 6 (Exhibit No. 10 marked) 7 BY MR. ZELLERS: 8 Q. Deposition Exhibit 10 also comes 9 from your report, Pages 15, 16, and 17. I'm 10 looking at the section of Deposition 11 Exhibit 10 that begins "Sources Considered." 12 Can you take a look at 13 Exhibit 10 and tell us what that refers to? 14 A. This is a list of sources that I 15 considered during the generation of my 16 report. 17 Q. What is the difference between 18 the references and the sources that you 19 considered? 20 A. Well, references are things that 21 I cited, and sources considered are things 22 that I looked at. 23 Q. Is the listing of sources 24 considered, Deposition Exhibit 10, a complete</p>	<p>Page 27</p> <p>Page 29</p>

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1 listing of the materials and sources that you
2 considered in preparing your report and in
3 developing your opinions in this case?

4 A. I believe so. I tried to
5 capture them all. I may have missed a few.

6 Q. How would you define the area of
7 expertise in which you're offering opinions
8 in this case?

9 A. Chemistry, molecular
10 pharmaceutics, formulation science,
11 pharmacology, toxicology.

12 Q. You consider yourself to be an
13 expert in each of those subject areas?

14 A. I consider myself to be an
15 expert in chemistry and pharmaceutical
16 science, as well as formulation matters.

17 Q. Anything else?

18 A. I think that's a pretty good
19 descriptor.

20 Q. Deposition Exhibit 7 is your
21 report in this case. Does that report
22 contain all of the opinions that you intend
23 to offer as a witness in this matter?

24 A. Yes.

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1 is the safety profile, and what's known about
2 it.

3 Q. Are the opinions which you're
4 rendering in this case limited to the
5 fragrance components of the talcum powder
6 products manufactured by Johnson & Johnson
7 Consumer Products, Inc.?

8 MS. O'DELL: Object to form.

9 A. I'm not sure I understand your
10 question.

11 BY MR. ZELLERS:

12 Q. The opinions that you are
13 rendering in this case, are they limited to
14 the fragrance components of the talcum powder
15 products manufactured by Johnson & Johnson
16 Consumer Products, Inc.?

17 A. Yes.

18 Q. And -- I'll strike that.

19 Can we agree that when I refer
20 to either products or talc products or baby
21 powder or Shower to Shower, that I'm
22 referring to the baby powder product
23 manufactured by Johnson & Johnson Consumer
24 Products, Inc., and the Shower to Shower

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1 Q. Is the report accurate?

2 A. I believe it is.

3 Q. Is it complete?

4 A. I believe so.

5 Q. Appendix A, which is a baby
6 powder fragrance chemical review, what was
7 the purpose of you preparing that appendix?

8 A. I was asked to review the
9 physical and chemical properties of each of
10 these fragrance chemicals, and I created that
11 list to capture the results of the evidence
12 that I found.

13 Q. How did you decide what
14 information to include in Appendix A?

15 A. Well, I was asked a couple of
16 questions, as described in my report, and
17 that seemed to be a logical framework in
18 which to collate the information.

19 And, frankly, it's consistent
20 with how a formulation scientist would
21 consider inactive ingredients when creating a
22 new composition. So you consider what are
23 the properties of these materials, both from
24 a chemical and biological perspective, what

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1 product formerly manufactured by Johnson &
2 Johnson Consumer Products, Inc.?

3 MS. O'DELL: Object to form.

4 A. I can agree to that
5 understanding.

6 BY MR. ZELLERS:

7 Q. You do not have an opinion -- or
8 not expressing any opinions in this case as
9 to whether or not talc products are
10 contaminated with asbestos. Is that right?

11 A. I was not asked to consider
12 that.

13 Q. Do you think you have produced
14 in this matter all of your file relating to
15 the expert work that you have done? And by
16 "produced," I mean in your report and as
17 supplemented by the exhibits that we've
18 marked here today.

19 A. I believe so.

20 Q. Did anyone assist you in
21 preparing your report?

22 A. Yes.

23 Q. Who assisted you in preparing
24 your report?

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Page 34

1 A. My wife.
2 Q. Your wife's name is?
3 A. Carrie, C-A-R-R-I-E, Asher,
4 A-S-H-E-R, Crowley.
5 Q. What did Ms. Asher Crowley do to
6 assist you in preparing your report in this
7 matter?
8 A. So she helped me identify some
9 of the fragrance chemicals.
10 Q. Anything else?
11 A. No.
12 Q. Do you bill separately for the
13 services of your wife, Ms. Asher Crowley?
14 A. Yes.
15 Q. When I go back and I look
16 through the invoices that have been produced
17 and that we've marked as Exhibit 2, will I
18 see references to Ms. Asher Crowley?
19 A. I think you'll see a different
20 bill rate for her time.
21 Q. Your bill rate is what?
22 A. \$600 an hour.
23 Q. Is your bill rate the same for
24 doing the review and preparation of the

1 A. No.
2 Q. Are you aware of any documents
3 relating to your review in this matter that
4 have not been identified either as sources
5 considered or in your reference list?
6 A. I don't think so. I mean, I've
7 seen some things in the news recently, but
8 they didn't impact my report.
9 MS. O'DELL: I'll just add for
10 the record: Other than what's been
11 marked as an exhibit here, just to make
12 it clear.
13 MR. ZELLERS: Yes.
14 A. I did my best to keep track of
15 and provide either -- in the references or,
16 you know, disclosed within sources considered
17 or within the appendices everything that I
18 looked at.
19 BY MR. ZELLERS:
20 Q. When you were -- strike that.
21 Were you first contacted by
22 Ms. O'Dell to become involved as an expert in
23 this matter?
24 A. No. Margaret Thompson initially

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1 report as it is for sitting for a deposition
2 here today?
3 A. Yes.
4 Q. Is your hourly rate of \$600 an
5 hour the same for any trial testimony or
6 hearing testimony that you may provide?
7 A. Yes.
8 Q. Ms. Asher Crowley, what is her
9 billing rate?
10 A. I think it was \$300 an hour.
11 Q. Any other services or assistance
12 that Ms. Crowley provided to you in terms of
13 preparing your report and developing your
14 opinions in this matter?
15 A. The opinions are mine. She did
16 not provide any opinions. She just simply
17 helped me identify some of the fragrance
18 chemicals.
19 Q. Is there anything else that she
20 did other than help to identify some of the
21 fragrance chemicals?
22 A. No.
23 Q. Anyone else who assisted you in
24 the preparation of your report?

1 contacted me.
2 Q. When Ms. Thompson contacted you,
3 you believe it was either April or May --
4 strike that.
5 You believe it was May of 2018?
6 A. That's about the right
7 timeframe.
8 Q. I'm looking at --
9 A. I don't recall the exact date.
10 Q. I'm looking at Deposition
11 Exhibit 2, and that appears to be the first
12 time entry that you have on this matter.
13 Does that refresh your recollection?
14 A. I got a contact. We went and
15 talked by phone and had a few additional
16 conversations before I agreed to take this
17 particular matter on. So that would
18 represent -- what you're looking at is the
19 first item I billed.
20 And at the time that we first
21 met, I was very busy with some other
22 projects, and I couldn't start working on
23 this immediately. So I don't recall the
24 exact date that we first met. I signed a

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<p>1 protective order and engagement letter. I 2 would consider that when we first got 3 engaged. We can get you, you know, those 4 dates if you'd like.</p> <p>5 Q. Does April or spring -- strike 6 that.</p> <p>7 Does April or May of 2018 sound 8 about right?</p> <p>9 A. Yes.</p> <p>10 Q. What did Ms. Thompson ask you to 11 do with respect to this matter?</p> <p>12 A. She indicated that she and her 13 colleagues were looking for an expert to 14 review the fragrance chemicals in the talcum 15 powder products and provide some additional 16 information.</p> <p>17 Q. When were you first asked to 18 prepare a report?</p> <p>19 A. I would say midsummer, June, 20 July.</p> <p>21 Q. Were you given any additional 22 instruction in terms of what plaintiffs' 23 counsel wanted you to do or were requesting 24 that you do in this matter around the time</p>	<p>Page 38</p> <p>1 deal with those objections at a later time. 2 So, once she has made her objection, you can 3 go ahead and answer the question as long as 4 you understand it.</p> <p>5 A. Okay. I'm sorry. Can you 6 repeat the question?</p> <p>7 Q. Sure. This additional topic 8 that you were asked to consider by 9 plaintiffs' counsel, you never got to the 10 point of considering it or formulating any 11 opinions. Is that right?</p> <p>12 A. I did put some time in 13 considering it, but I ran out of time to 14 properly research it, and I think I won't be 15 rendering an opinion on it today.</p> <p>16 Q. Any other topics that you were 17 asked to address by either Ms. Thompson or 18 any of the counsel for plaintiffs in this 19 matter?</p> <p>20 A. No.</p> <p>21 Q. Originally defense counsel were 22 provided with a report that was dated 23 November 12th of 2018. We then received a 24 second slightly revised report around</p>
<p>1 that you were asked to prepare a report?</p> <p>2 A. I mean, the two questions that 3 appear in my report were the instructions.</p> <p>4 Q. Did plaintiffs' counsel in the 5 talc MDL ask you to address any other 6 questions?</p> <p>7 A. I was briefly asked to consider 8 reviewing the flotation process used in the 9 talc manufacturing.</p> <p>10 Q. Did you decline that?</p> <p>11 A. I ran out of time. I didn't 12 have time.</p> <p>13 Q. You are expressing no opinions, 14 then, with respect to the flotation process 15 involved in the talc processing. Is that 16 right?</p> <p>17 MS. O'DELL: Object to form. 18 You may answer.</p> <p>19 A. Sorry. I couldn't hear you.</p> <p>20 MS. O'DELL: You may answer.</p> <p>21 BY MR. ZELLERS:</p> <p>22 Q. Yeah. As we go along today, 23 Counsel will make some objections. She's 24 doing that just to protect the record. We'll</p>	<p>Page 39</p> <p>1 December 4th of 2018. Are you familiar with 2 that?</p> <p>3 A. No. I think -- I think 4 Ms. O'DELL told me that they originally 5 submitted an unsigned copy, and when they 6 recognized that, they resubmitted the signed 7 copy, something to that effect.</p> <p>8 MS. O'DELL: I would just state 9 for the record the incorrect PDF was 10 put in the Dropbox. That's what 11 happened. So -- and then once we 12 realized that, we provided the correct 13 version.</p> <p>14 BY MR. ZELLERS:</p> <p>15 Q. Deposition Exhibit 7 is your 16 final report with respect to this matter. Is 17 that right?</p> <p>18 A. I believe so.</p> <p>19 Q. That is the report that contains 20 all of the opinions that you intend to 21 express in the talc MDL. Is that right?</p> <p>22 A. Yes.</p> <p>23 Q. Have you been disclosed as an 24 expert in any other talcum powder proceeding</p>

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1 aside from this matter, the talc MDL?
2 A. No.
3 Q. Have you done any expert work or
4 consulting work in any other talcum powder
5 matters?
6 A. No.
7 Q. What percentage -- well, strike
8 that.
9 You work for a consulting firm.
10 Is that right?
11 A. I own a consulting firm.
12 Q. The name of that consulting firm
13 is what?
14 A. Theridian Technologies, LLC.
15 Q. Do you devote 100 percent of
16 your professional time to your work for that
17 consulting firm?
18 A. No.
19 Q. What percent or -- strike that.
20 What percent of your
21 professional time do you devote to your
22 consulting firm Theridian Technologies?
23 A. Somewhere between two-thirds and
24 three-quarters, I would say.

1 A. Yes.
2 Q. Are there any employees of
3 Theridian Technologies, LLC, other than
4 yourself?
5 A. My wife.
6 Q. Any others?
7 A. No.
8 Q. You -- strike that.
9 What percent of your time at
10 Theridian Technologies involves legal or
11 litigation consulting?
12 A. Time, probably 25 percent.
13 Q. In terms --
14 A. I mean, it varies. I mean,
15 sometimes it's more than others, but over the
16 course of a year, maybe 25 percent.
17 Q. In terms of income of Theridian
18 Technologies, what percent of income is
19 accounted for by legal consulting work?
20 A. Again, it varies year to year.
21 It's probably somewhere in the 10 to
22 20 percent range.
23 Q. You told us that you serve as an
24 expert in other cases. Is that right?

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1 Q. How do you spend your other
2 professional time?
3 A. I co-founded a startup called --
4 it was originally called Oticus Laboratories.
5 It's -- it's been renamed Oticara
6 Corporation. I've recently closed a
7 significant funding round. We're doing
8 clinical studies.
9 And I serve on the board of
10 another company, so --
11 THE REPORTER: Of another
12 company?
13 THE WITNESS: Yes.
14 THE REPORTER: Try to keep your
15 voice up for me.
16 THE WITNESS: Sorry.
17 BY MR. ZELLERS:
18 Q. What is the name of the company
19 that you serve on the board of?
20 A. Texas EnteroSorbents.
21 Q. Is it accurate that anywhere
22 from two-thirds to three-quarters of your
23 professional time are spent by you working as
24 a consultant?

1 A. Yes.
2 Q. Is this the first time that you
3 have served as an expert in a case involving
4 an allegation of personal injuries?
5 A. Yes.
6 Q. Is this the first time that you
7 have served as an expert in a product
8 liability matter?
9 A. Yes.
10 Q. The depositions that you have
11 given -- strike that.
12 You have given, you thought,
13 four or five depositions previously?
14 A. I think four.
15 Q. Two of the matters you've
16 identified. One as Grunenthal versus --
17 A. It's pronounced Grunenthal.
18 Q. Grunenthal versus Teva, and then
19 a second matter of Ciprodox. What types of
20 matters were those?
21 A. Patent disputes.
22 Q. What areas of expertise were you
23 testifying in?
24 A. Chemistry, formulation,

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1 stability.

2 Q. Were you serving as an expert
3 for the plaintiff or the defense in those
4 matters?

5 A. One was plaintiff. The other
6 was defense.

7 Q. Which one was plaintiff?

8 A. So the Grunenthal case I was --
9 the generic companies were suing Grunenthal,
10 so I was working for the generic companies.
11 I presume that's the plaintiffs.

12 In the Ciprofex matter, I was --
13 Alcon Laboratories, I was working on their
14 behalf. They were the innovator company.

15 Q. What other matters have you
16 provided deposition testimony in?

17 A. I was an expert on behalf of
18 Novartis. The drug was Myfortic. That was
19 more than five -- five years ago, though.

20 Q. Okay. That testimony was where?

21 A. The deposition was in -- in
22 Canada in February.

23 Q. Do you remember approximately
24 when?

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1 A. No. I'll be getting deposed on
2 January 23rd in another patent dispute in San
3 Francisco.

4 Q. The name of that matter is what?

5 A. The product is Niaspan. I'm
6 working on behalf of the innovator company,
7 AbbVie. It is also a patent dispute.

8 Q. Any other testimony that you
9 have provided?

10 A. I don't think so.

11 Q. Any trial testimony?

12 A. Never been at trial.

13 Q. Any of the matters in which you
14 previously provided testimony, have they
15 involved fragrance chemicals?

16 A. No.

17 Q. Have they involved any issues
18 relating to fragrance chemicals?

19 MS. O'DELL: Object to form.

20 A. No.

21 BY MR. ZELLERS:

22 Q. Are you serving presently as an
23 expert in any other matters?

24 A. Yes.

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1 A. I remember it was, like, minus
2 70 degrees outside, and I can't tell you what
3 year it was.

4 Q. Can you estimate for us?

5 A. I think it was somewhere around
6 2011 or '12, perhaps.

7 Q. That also was a patent dispute?

8 A. Patent dispute, yeah.

9 Q. The fourth case that you've
10 rendered testimony in, was that a contract
11 case?

12 A. Yes.

13 Q. When did you provide that
14 testimony?

15 A. 2010, I believe.

16 Q. What was the matter name, if you
17 remember?

18 A. Michael Crowley v. PharmaForm
19 and Akela.

20 Q. That was a personal contract
21 dispute that you had?

22 A. Yeah.

23 Q. Any other deposition testimony
24 you have provided?

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1 Q. How many?

2 A. Well, I just told you about the
3 Niaspan matter. I'm also working on -- it's
4 called IPR, inter partes review, which is
5 also a patent dispute, on behalf of Pfizer.
6 The defendant is Intellipharmaceutics, and
7 the product is called Evzio. It's a
8 naloxone --

9 Q. Any other expert matters?

10 MS. O'DELL: Excuse me, sir.
11 Were you finished?

12 THE WITNESS: No.

13 MS. O'DELL: Okay. You may
14 finish your answer. I'm sorry.

15 A. Yeah. The product is Evzio. I
16 have been engaged on another matter. I have
17 not yet agreed to take it.

18 BY MR. ZELLERS:

19 Q. What matter is that?

20 A. It's a pharmaceutical patent
21 dispute. I don't know the name of the
22 product. I've just looked at the patent, and
23 I'm going to talk to the counsel that's
24 engaged me to learn more to decide on whether

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1 or not I think they have a position that I
2 can support.

3 Q. All of the expert witness work
4 that you have done has related to patent
5 disputes. Correct?

6 A. That's correct.

7 Q. None of the expert witness work
8 that you have been engaged in other than this
9 matter relates to or involves fragrance
10 chemicals. Correct?

11 MS. O'DELL: Object to form.

12 A. I have not provided testimony
13 regarding fragrance chemicals before.

14 BY MR. ZELLERS:

15 Q. Have you ever been retained in a
16 case involving asbestos?

17 A. No.

18 Q. Have you ever been retained in a
19 case involving cosmetic products?

20 A. No.

21 Q. Your curriculum vitae accurately
22 describes your education background. Is that
23 right?

24 A. Yes.

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1 flavor division -- actually, multiple flavor
2 divisions, and I worked as a chemist there.
3 Texas EnteroSorbents makes a
4 clay product that is used in facial masks. I
5 helped formulate that clay.

6 Q. Any other involvement that
7 you've had with any type -- well, strike
8 that.

9 Would you describe those
10 chemicals as fragrance chemicals?

11 A. I've used fragrance chemicals.

12 Q. In terms of the work that you've
13 just described for us?

14 A. Well, there's no fragrance in
15 the facial mask. Warner-Jenkinson made
16 fragrances. I've used fragrances in
17 pharmaceutical products.

18 I've formulated a prenatal
19 vitamin that we put ethyl vanillin in to add
20 a scent -- an agreeable scent because the
21 minerals present were unpleasant to pregnant
22 moms. So I have experience working with
23 fragrances and flavors.

24 Q. The company was Warner- --

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1 Q. You majored in chemistry at the
2 University of Missouri. Correct?

3 A. Yes.

4 Q. You received a Master of Arts in
5 organic chemistry at Washington University
6 St. Louis in 1991. Is that right?

7 A. Yes.

8 Q. And a Ph.D. in molecular
9 pharmaceutics in 2003. Is that right?

10 A. Yes.

11 Q. Any other former -- strike that.

12 Any additional formal education?

13 A. No.

14 Q. None of the companies that you
15 currently work for or serve on the board of
16 directors manufacture and produce cosmetic
17 products. Is that right?

18 A. No. I worked at Warner-
19 Jenkinson. Warner-Jenkinson is now known as
20 Sensient Technologies. Warner-Jenkinson is
21 the world's largest manufacturer of
22 colorants, that includes D&C colorants used
23 for cosmetics. Warner-Jenkinson is where the
24 flavor for 7-Up was invented, and they have a

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1 A. Yeah, Warner-Jenkinson. If you
2 turn to Page 207, Warner-Jenkinson Company in
3 St. Louis.

4 Q. You worked at Warner-Jenkinson
5 from January of 1992 to July of 1995. Is
6 that right?

7 A. Yes.

8 Q. That was your first position
9 after completing your education. Is that
10 right?

11 A. After I received my Master's
12 degree.

13 Q. Your position at Warner-
14 Jenkinson was what?

15 A. After I received my Master's
16 degree, my position was chemist.

17 Q. That was your experience with
18 cosmetic products other than the facial mask
19 that you described for us. Is that correct?

20 MS. O'DELL: Object to form.

21 A. That wasn't the only experience
22 I had with cosmetic products.

23 BY MR. ZELLERS:

24 Q. What other experience other

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1 than -- and let me make sure that I
2 understand. The facial product that you had
3 some involvement with, where was that at?

4 A. So Texas EnteroSorbents sells a
5 natural product, clay. It's actually a
6 silicate -- calcium aluminum silicate that's
7 used in facial masks.

8 Q. Okay. You serve on the board of
9 directors at Texas EnteroSorbents. Is that
10 right?

11 A. Yes.

12 Q. Have you ever been an employee
13 for that company?

14 A. No.

15 Q. Have you ever been a consultant
16 for that company?

17 A. Yes.

18 Q. And what was your contribution
19 to the facial clay that they sell?

20 A. An investor wanted to create
21 products -- facial clay products and other
22 cosmetics with the clay, and I connected him
23 with subcontracting companies that could help
24 facilitate the development of those and

1 Q. You have no formal training in
2 toxicology?

3 MS. O'DELL: Object to form.
4 A. I took tox classes in grad
5 school.

6 BY MR. ZELLERS:

7 Q. Other than that, you have no
8 formal training. Correct?

9 MS. O'DELL: Object to form.
10 A. That sounds like training to me.

11 BY MR. ZELLERS:

12 Q. Other than what you testified
13 to, you have no formal training in
14 toxicology. Correct?

15 A. I don't think that question is
16 appropriate.

17 Q. You don't understand that
18 question?

19 A. I would consider taking graduate
20 level classes as formal training.

21 Q. Other than the graduate level
22 class or classes that you've described for
23 us, have you had any other formal education
24 in toxicology?

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1 served as a technical consultant to the
2 creation of compositions.

3 Q. Is that a commercial product?

4 A. It is.

5 Q. The brand name is what?

6 A. I don't know. They -- it's
7 called Reavari (phonetic). I understand you
8 can go buy the facial masks and Neiman Marcus
9 and some other places. It's sold under
10 multiple names, but I can't -- I couldn't
11 tell you the name of the end user product.

12 Q. What other experience other than
13 what you've described for us have you had
14 with cosmetic products?

15 A. I think that's most of it.

16 Q. You are not a medical

17 toxicologist. Correct?

18 A. That's correct.

19 Q. You do not have a Ph.D. in

20 toxicology. Correct?

21 A. That's correct.

22 Q. You do not hold yourself out as

23 a toxicologist. Is that right?

24 A. Yes.

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1 A. Yes.

2 Q. Tell us what that is.

3 A. So I was a co-owner of a company
4 called PharmaForm, and we worked with
5 pharmaceuticals. We used a company called
6 SafeBridge out of the Bay area, San
7 Francisco, to evaluate the safety, toxicity,
8 and pharmacology of new molecular entities
9 prior to us bringing them in-house and
10 working with them.

11 So SafeBridge came in and did
12 some industrial safety and toxicology
13 training with our team, and we would engage
14 them on each new drug substance prior to
15 working on it.

16 Q. You had a toxicologist come in
17 and provide you and others with additional
18 training. Is that right?

19 A. Yes.

20 Q. You are not a regulatory expert.
21 Is that right?

22 A. No.

23 Q. You are not --

24 A. Well, actually -- I mean, how do

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1 you want to define "expert"? I write
2 submissions to the FDA.

3 Q. Are you an expert in terms --
4 well, strike that.

5 Do you consider yourself to be a
6 regulatory expert?

7 MS. O'DELL: Object to form.

8 A. I'm more than competent in
9 regulations.

10 BY MR. ZELLERS:

11 Q. Okay.

12 A. And my wife is a regulatory
13 affairs and quality assurance --

14 Q. You're being deposed here today.

15 A. Yeah.

16 Q. My question is: Do you consider
17 yourself to be a regulatory expert?

18 A. I consider myself --

19 MS. O'DELL: Objection -- excuse
20 me.

21 A. -- to be very competent in
22 understanding regulations.

23 MS. O'DELL: Let me just
24 insert -- object to the form of the

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1 A. No.

2 Q. For what company?

3 A. Pain Therapeutics. They're a
4 consulting client. They're not on my CV.

5 Q. What product were you testifying
6 to before the FDA on?

7 A. It's a new form of oxycodone.

8 Q. Was the company attempting to
9 obtain regulatory approval?

10 A. Yes.

11 Q. What hearing or type of
12 proceeding was this before the FDA?

13 A. It was an FDA advisory committee
14 meeting.

15 Q. You presented on behalf of your
16 client at the FDA advisory committee meeting.
17 Is that right?

18 A. That's correct.

19 Q. Do you believe that qualifies
20 you as a regulatory expert?

21 A. I have said this, I think, three
22 times now, Counselor. I am more than
23 competent in understanding regulations.

24 Q. You are not an expert in the FDA

1 question. Sorry. Excuse me. Give me
2 just a second to get that in there.

3 BY MR. ZELLERS:

4 Q. Is that a "yes" or is that a
5 "no"?

6 A. I think I answered your
7 question, Counselor.

8 Q. Do you consider yourself to be a
9 regulatory expert, yes or no?

10 A. I'm more than competent in
11 understanding regulations.

12 Q. I understand you consider
13 yourself competent to understand regulations.
14 Has anybody come to you and asked you to
15 serve as a regulatory expert in any legal
16 matter?

17 A. Not in any legal matter, but in
18 June of this year I was presenting to the
19 FDA.

20 Q. What did you present to the FDA
21 on in June?

22 A. A new drug application.

23 Q. And this was a new drug
24 application for your company?

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1 regulatory process for cosmetic products.
2 Correct?

3 MS. O'DELL: Object to form.

4 A. The FDA has very limited
5 cosmetic regulations.

6 BY MR. ZELLERS:

7 Q. I need you to answer my question
8 as best you can.

9 You are not an expert in the FDA
10 regulatory process for cosmetic products. Is
11 that correct?

12 MS. O'DELL: Object to form.
13 You may answer.

14 A. I've read them, and I understand
15 them, and I expect to opine on them today,
16 so --

17 BY MR. ZELLERS:

18 Q. That is the extent of your
19 expertise with respect to the FDA regulatory
20 process for cosmetic products. Correct?

21 MS. O'DELL: Object to form.

22 A. I've certainly applied them in
23 creating cosmetic products, Counselor.

24

1 BY MR. ZELLERS:

2 Q. Anything else?

3 A. Anything else with regard to?

4 Q. Yes. FDA regulatory expertise
5 with cosmetic products.

6 MS. O'DELL: Object to form.

7 A. I don't understand your
8 question.

9 BY MR. ZELLERS:

10 Q. You're not a medical doctor.

11 Correct?

12 A. No.

13 Q. You don't treat patients?

14 A. No.

15 Q. You are not a pathologist?

16 A. No.

17 Q. You have no formal training or
18 education in pathology. Correct?

19 A. That's correct.

20 Q. You've never done a pathological
21 exam. Correct?

22 A. No.

23 Q. And you have never authored a
24 pathology report involving ovarian cancer.

1 than the book that we marked as Deposition

2 Exhibit 5?

3 A. Flavors and Flavonoids was a
4 book that I recall looking at several years
5 ago. Generally, you know, you pick up the
6 phone, and you call International Flavors &
7 Fragrances or any number of fragrance houses.
8 Also there are some consultants that we would
9 engage. We developed oral compositions that

10 we would do e-tongue studies with to
11 understand taste profiles of new drugs and if
12 flavors or sweeteners were required to help
13 with palatability. I've done work with
14 pediatric compositions, and those are often
15 flavored.

16 Q. What experts or consultants
17 would you go to if you had questions about
18 fragrance chemicals?

19 A. There's a guy named David Tze.
20 I can't remember his company, but they're
21 well-known for, you know, using e-tongue and
22 flavoring assistance with compositions.

23 Q. Anyone else or any other
24 companies or groups?

1 Is that right?

2 A. That's correct.

3 Q. Have you ever worked with a
4 cosmetic product that is applied in the
5 peroneal region?

6 A. No.

7 Q. Before being contacted by
8 Ms. Thompson and the attorneys for plaintiffs
9 in the talc MDL litigation, did you keep up
10 to date on the topic of fragrance chemicals
11 by reviewing peer-reviewed literature?

12 A. When I needed to. I mean, at
13 various times I would reach out and see what
14 I needed to know about certain fragrances.

15 Q. Would you do that on a routine
16 basis, or would you do that in connection
17 with a particular project or assignment?

18 A. In a particular -- in connection
19 with a project.

20 Q. What journals would you review
21 to try to educate yourself on the topic of
22 fragrance chemicals?

23 A. I looked at books.

24 Q. What books did you review other

1 A. I mean, we contacted a number of
2 different flavor companies that have got
3 excellent technical service to help identify,
4 you know, flavors and products available.

5 Q. You have never written or
6 published on the topic of fragrance
7 chemicals. Is that right?

8 A. That's correct.

9 Q. You have never written or
10 published on the topic of talcum powder.

11 Correct?

12 A. No.

13 Q. What writings or publications
14 have -- do you have with respect to talcum
15 powder?

16 A. Well, I've formulated products
17 that are approved by the FDA that have talcum
18 powder in it.

19 Q. What products?

20 A. I would have to -- well, Thiola.
21 It dissolves kidney stones. It's a film
22 coating. We put talc in the film coating.

23 Q. Is that a marketed product?

24 A. Yes, it's commercially

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1 available.
2 Q. Who is the manufacturer of
3 Thiola?
4 A. Mission Pharmacal in San
5 Antonio.
6 Q. When -- strike that.
7 What was your involvement with
8 that product?
9 A. I was the formulator.
10 Q. When were you involved with the
11 formulation of Thiola?
12 A. That would have been sometime
13 between 1995 and 2000.
14 Q. What company were you with at
15 the time?
16 A. Mission Pharmacal, the owner of
17 the product.
18 Q. My question to you, though, was:
19 Have you ever written or published on talcum
20 powder or any issues relating to talcum
21 powder?
22 A. I have -- I'm almost certain
23 that some of my patents disclose the use of
24 talcum powder, but I have not authored any

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1 before getting involved in this litigation.
2 Correct?
3 A. That's correct.
4 Q. You -- strike that.
5 Have you ever -- other than your
6 involvement with Thiola and helping Mission
7 Pharmacal back in 1995 to January of 2000
8 with respect to this product Thiola, you've
9 had no communications with the FDA regarding
10 talcum powder. Correct?
11 MS. O'DELL: Object to the form.
12 A. I don't believe I've ever had a
13 communication with the FDA about talcum
14 powder. I mean, I've met with FDA on
15 multiple occasions, and I have worked on
16 products that have talcum powder in it, but I
17 don't believe that -- I've certainly never
18 had a discussion with the FDA about any of
19 the issues with respect to talcum powder
20 safety.
21 BY MR. ZELLERS:
22 Q. Or anything else other than
23 perhaps in connection with Thiola back in
24 1995 to 2000?

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1 papers specific to, you know, concerns with
2 asbestos and ovarian cancer and so forth,
3 so --
4 Q. Or inflammation or irritation.
5 Correct?
6 MS. O'DELL: Object to form.
7 A. I haven't -- I haven't published
8 on that with respect to talcum powder, no.
9 BY MR. ZELLERS:
10 Q. You also have not, with respect
11 to all of those subjects, done any
12 independent research. Fair?
13 MS. O'DELL: Object to the form.
14 A. I have reviewed the literature.
15 BY MR. ZELLERS:
16 Q. Other than going out and
17 reviewing articles or reviewing textbooks,
18 you have not done any independent research
19 with respect to fragrance chemicals, cancer,
20 asbestos, inflammation?
21 A. No, I have not.
22 Q. You have -- strike that.
23 You had formulated no opinions
24 regarding the ingredients in talcum powder

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1 MS. O'DELL: Excuse me. Object
2 to form.
3 A. I don't believe so.
4 BY MR. ZELLERS:
5 Q. What product have you been
6 involved in that contains talcum powder other
7 than Thiola?
8 A. Warner-Jenkinson made film
9 coatings -- it's called SpectraBlend and
10 SpectraSpray, and talc was a component of
11 those products.
12 Q. Were you --
13 A. Talc was also used in their
14 cosmetics.
15 Q. Were you personally involved in
16 any products involving talcum powder at
17 Warner-Jenkinson?
18 A. Yes.
19 Q. What products -- or strike that.
20 In what way were you personally
21 involved with talcum powder?
22 A. Just SpectraBlend and
23 SpectraSpray had talcum powder in it.
24 Q. What was your involvement in

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1 that?
2 A. I was providing technical
3 service, product development support for
4 those two products.
5 Q. Did those products ever become
6 marketed?
7 A. Well, I don't know how to answer
8 your question. So those would be used by
9 Warner-Jenkinson's customers in their
10 products that were marketed. So, for
11 example, we worked with, you know, McNeil on
12 the Tylenol gel caps. SpectraBlend and
13 SpectraSpray were used as part of those
14 products. We worked on Tylenol PM, which
15 are --
16 Q. You would sell to folks who
17 would use the --
18 A. Spectra --
19 Q. -- Warner-Jenkinson product in
20 their product?
21 A. Yeah, that's correct.
22 Q. Any other talcum powder
23 experience other than what you've told me?
24 A. I mean, it's been used in a

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1 MR. ZELLERS: Mr. Court
2 Reporter, you speak up as well if you
3 need to take a break.
4 BY MR. ZELLERS:
5 Q. Are we good?
6 A. Let's go another ten minutes and
7 take a break at 10:30. Does that sound
8 reasonable?
9 Q. Yes, although I've got a topic
10 here that I want to finish.
11 A. Okay.
12 Q. So it may take me 15 minutes or
13 20 minutes.
14 A. That's okay.
15 Q. But let me just finish this
16 topic, and then --
17 MS. WUNDERLICH: Can I just ask
18 that you keep your voice up. I can't
19 hear you very well down here,
20 especially with a lot of noise from
21 outside.
22 MS. O'DELL: Are you referring
23 to the witness or --
24 MS. WUNDERLICH: The witness,

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1 number -- I mean, it's been used as a glider
2 for making tablets and filling capsules and
3 so forth. I feel confident we used it at
4 PharmaForm, too.
5 So, I mean, it's -- it's
6 something I've used at multiple points during
7 my 20-plus years experience.
8 Q. Have you ever been involved in a
9 safety or risk assessment analysis of talcum
10 powder other than in this case?
11 A. No.
12 Q. Have you ever communicated with
13 the FDA regarding any issues relating to
14 ovarian cancer?
15 A. No.
16 Q. Any communications with Health
17 Canada regarding talcum powder?
18 A. No.
19 Q. Any communications with Health
20 Canada regarding ovarian cancer?
21 A. No.
22 Q. I did not tell you this in the
23 beginning, but anytime you or any counsel
24 need to take a break, speak up.

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1 yes.
2 THE WITNESS: If you can't hear
3 me, just give me a cue, and I'll try to
4 repeat. Are you able to hear me okay?
5 Can you hear me okay?
6 BY MR. ZELLERS:
7 Q. Were you under any time pressure
8 in terms of analyzing the issues that you
9 were asked to analyze in this case by
10 plaintiffs in developing your opinions and
11 preparing your report?
12 MS. O'DELL: Object to form.
13 A. I wish I would have had more
14 time. There was an awful lot of stuff to
15 review. There was approximately 175
16 fragrance chemicals between the two of them,
17 and I tried to review as much of the
18 available information as I could find.
19 BY MR. ZELLERS:
20 Q. Do you have an estimate as to
21 the amount -- total amount of time that
22 you've spent on this matter?
23 A. No. I'd have to look at those
24 invoices and sum it all up, which I have not

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1 done. 2 Q. Would you have spent more time 3 if you had more time in terms of doing 4 research and reviewing matters to prepare 5 your opinions in this matter? 6 A. Yeah. I mean, I -- I would have 7 liked a little bit more time, but I'm 8 comfortable with the opinions. 9 Q. Did plaintiffs' counsel provide 10 you with any of the articles or data or 11 documents that you referenced in your report? 12 A. Yes. So I -- you know, I did 13 all the primary literature searching and 14 searched the databases and so forth. The 15 documents in the sources relied upon list 16 that -- that are from the case -- you know, 17 I-M-E-R-Y -- the Imerys documents and the J&J 18 numbered documents, those were produced by 19 counsel. But everything else I found on my 20 own. 21 Q. If we look, then, at your 22 report, which includes Deposition Exhibits 9 23 and 10, your reference list and your sources 24 considered list, the only documents and	Page 74	1 BY MR. ZELLERS: 2 Q. Is that correct -- 3 A. Yes. 4 Q. -- Dr. Crowley? 5 A. Yeah. 6 Q. Any other articles, data, 7 documents, or materials that were provided to 8 you by plaintiffs' counsel in connection with 9 your review of this matter? 10 A. They may have emailed me some 11 information along the way, but to the best of 12 my recollection, that's the key pieces. 13 Q. If they emailed you any articles 14 or data or documents, would you have included 15 those in your sources considered list? 16 A. I think so. I mean, at one 17 point I received an email that pointed to the 18 J&J website in which, you know, the quality 19 and purity of the ingredients and the quality 20 process at J&J was disclosed, but I don't 21 think that's in my sources considered list. 22 Q. Anything else that -- strike 23 that. 24 Any other source that you	Page 76
1 materials that were provided to you by 2 plaintiffs' counsel were the Johnson & 3 Johnson documents and the Imerys documents. 4 Correct? 5 A. I believe so. Well, they gave 6 me the Thomas Dydek report. And I think at 7 one point I was given the Canadian Ministry 8 of Health or Health Ministry review of talcum 9 powder. And -- 10 Q. Anything else? 11 A. I think that is everything. 12 MS. O'DELL: Just for the 13 record, I would add the supplemental 14 answers to plaintiffs' second set of 15 interrogatories from the Ingram case 16 were also litigation materials that 17 were provided to Dr. Crowley, and those 18 are the list of fragrance chemicals. 19 THE REPORTER: I'm sorry. The 20 list of what? 21 MS. O'DELL: Fragrance 22 chemicals. 23 A. Yeah. 24	Page 75	1 considered in preparing your report in this 2 matter that is not identified in either the 3 reference list, the body of the report, or 4 your sources considered? 5 A. I think I may have looked at a 6 toxicology book or two just to refresh myself 7 on some of those things. These are textbooks 8 that I had from graduate school. 9 I probably looked at -- you 10 know, refreshed myself on a few items, but 11 I -- as I've said previously, I believe I 12 made every effort to disclose everything that 13 I considered and relied upon. 14 Q. What toxicology books did you 15 look at to refresh your recollection on those 16 issues? 17 A. They're sitting on my bookshelf 18 at home. I'd have to go look. I can't even 19 remember who the authors are right now. 20 Q. Anything else that you reviewed 21 or considered other than what's contained in 22 your report, the reference list, and the 23 sources considered list? 24 MS. O'DELL: Object to the form.	Page 77

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<p>1 In addition to --</p> <p>2 MR. ZELLERS: In addition to his</p> <p>3 testimony.</p> <p>4 MS. O'DELL: His testimony and</p> <p>5 the appendices?</p> <p>6 MR. ZELLERS: Yes. And he told</p> <p>7 me early on that he considers the</p> <p>8 appendices to be part of his report.</p> <p>9 MS. O'DELL: Fair enough. I</p> <p>10 just wanted to make that clear.</p> <p>11 A. As I said, I've made every</p> <p>12 effort to, you know, make sure that the stuff</p> <p>13 I relied upon is in that list and/or cited.</p> <p>14 BY MR. ZELLERS:</p> <p>15 Q. Did you --</p> <p>16 A. I don't believe there's anything</p> <p>17 that I've missed.</p> <p>18 Q. Did you -- are you finished?</p> <p>19 A. Yeah.</p> <p>20 Q. Did you review any expert</p> <p>21 reports from any other plaintiff expert in</p> <p>22 the talc MDL?</p> <p>23 A. After I submitted my report,</p> <p>24 they were circulated -- some of the other</p>	<p>Page 78</p> <p>1 A. No.</p> <p>2 Q. Did you review Dr. Plunkett's</p> <p>3 deposition transcript, which was taken in</p> <p>4 December of 2018.</p> <p>5 A. Yesterday they read --</p> <p>6 Ms. O'Dell --</p> <p>7 MS. O'DELL: Don't --</p> <p>8 THE WITNESS: That's privileged?</p> <p>9 MS. O'DELL: That's privileged.</p> <p>10 Don't disclose anything that we've</p> <p>11 discussed.</p> <p>12 THE WITNESS: Okay.</p> <p>13 BY MR. ZELLERS:</p> <p>14 Q. My question is: Have you</p> <p>15 reviewed Dr. Plunkett's deposition</p> <p>16 transcript?</p> <p>17 A. No.</p> <p>18 Q. Do you have a general</p> <p>19 understanding of who Dr. Plunkett is?</p> <p>20 A. No.</p> <p>21 Q. Do you have a general</p> <p>22 understanding of her opinions in this matter?</p> <p>23 A. No.</p> <p>24 Q. You were asked to make certain</p>
<p>1 experts were circulated. I -- to say</p> <p>2 "review" would be an overstatement. I think</p> <p>3 I looked at title pages to see what people</p> <p>4 opined on.</p> <p>5 I think there was one report</p> <p>6 that I even kind of flipped through the whole</p> <p>7 thing. Most of mine I did not read anything</p> <p>8 other than the title page.</p> <p>9 Q. What expert report did you at</p> <p>10 least flip through?</p> <p>11 A. I don't remember the name of the</p> <p>12 expert, but he was opining on detection</p> <p>13 methods and testing methods.</p> <p>14 Q. Any other expert reports that</p> <p>15 you reviewed relating to the talcum powder</p> <p>16 issues?</p> <p>17 A. No, I don't think so.</p> <p>18 Q. Did you review any expert</p> <p>19 reports other than Dr. Dydek's report from</p> <p>20 any of the other talcum powder cases?</p> <p>21 A. No.</p> <p>22 Q. Have you reviewed any deposition</p> <p>23 or trial transcripts from any of the talcum</p> <p>24 powder cases?</p>	<p>Page 79</p> <p>1 assumptions in forming your opinions. Is</p> <p>2 that right?</p> <p>3 A. Yes.</p> <p>4 Q. On Page 11 of your report -- and</p> <p>5 feel free to refer to it if you need to --</p> <p>6 you were asked to assume that talcum powder</p> <p>7 can migrate from the perineum to the upper</p> <p>8 genital tract. Is that right?</p> <p>9 A. Yes.</p> <p>10 Q. Your opinion that fragrance</p> <p>11 chemicals contribute to the inflammatory</p> <p>12 properties, toxicity, or potential</p> <p>13 carcinogenicity of the products is dependent</p> <p>14 on plaintiffs' ability to prove that talcum</p> <p>15 powder can migrate from the vagina to the</p> <p>16 upper genital tract. Correct?</p> <p>17 MS. O'DELL: Object to form.</p> <p>18 A. No, not necessarily. A number</p> <p>19 of these fragrance chemicals are absorbed</p> <p>20 through skin, and several of them are</p> <p>21 permeation enhancers, which means that they</p> <p>22 will actually help promote other things from</p> <p>23 being absorbed, metabolized, distributed, and</p> <p>24 eliminated. So, regardless of whether that</p>

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1 assumption holds or not, it doesn't affect my
2 opinion.

3 BY MR. ZELLERS:

4 Q. Is it your testimony that a skin
5 irritant can produce or increase the risk for
6 ovarian cancer?

7 MS. O'DELL: Object to the form.

8 A. It's certainly possible, yeah.

9 BY MR. ZELLERS:

10 Q. Explain how a skin irritant can
11 be associated with an increased risk of
12 ovarian cancer?

13 A. An irritation produces an
14 inflammatory response.

15 Q. It produces an inflammatory
16 response in the area of the irritation. Is
17 that right?

18 A. Yes. But also, I mean, those
19 inflammatory chemicals travel throughout the
20 human body. So increased levels of
21 inflammation have been associated with a
22 higher risk of cancers.

23 Q. Skin irritation, has it been
24 associated with an increased risk of ovarian

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1 A. Just report the facts and rely
2 upon the facts to form the basis of the
3 opinion. There's no bias here, Counselor.

4 Q. Was there any additional
5 information that you need to fully and fairly
6 evaluate the questions that are set forth in
7 your report?

8 A. I don't believe so. I did my
9 best to examine the totality of the evidence.

10 Q. Do you agree that if you did not
11 have all the information, that your opinions
12 could be biased?

13 MS. O'DELL: Object to form.

14 A. I don't believe that they are.

15 BY MR. ZELLERS:

16 Q. If you didn't have all the
17 relevant information, could your opinions be
18 unfounded or incomplete?

19 MS. O'DELL: Object to --

20 A. I --

21 MS. O'DELL: Excuse me. Object
22 to the form.

23 A. I'm very comfortable that I
24 examined and used generally accepted

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1 cancer?

2 A. Skin irritation?

3 Q. Yes.

4 A. I wasn't asked to opine --

5 Q. Inflammation of the skin, has
6 that been associated with an increased risk
7 of ovarian cancer?

8 MS. O'DELL: Object to form.

9 A. I wasn't asked to offer that
10 opinion.

11 BY MR. ZELLERS:

12 Q. And you're not offering those
13 opinions. Correct?

14 A. That's correct.

15 Q. Any other assumptions that
16 you're making in forming your opinions here
17 today?

18 A. No.

19 Q. In reaching your opinions, would
20 you agree it's important for you to address
21 the questions asked and review the data in a
22 fair and impartial way?

23 A. Yes.

24 Q. Why is that important?

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1 practices to gather the information and then
2 form opinions upon which that evidence is
3 based.

4 BY MR. ZELLERS:

5 Q. I --

6 A. So there is no biased -- bias
7 associated with understanding facts.

8 Q. Do you agree that scientists and
9 experts in litigation should be ethical and
10 honest?

11 A. Yes.

12 Q. You reference sources from the
13 EPA in your report. Is that right?

14 A. Yes.

15 Q. Is the EPA a reputable
16 organization?

17 MS. O'DELL: Object to the form.

18 It's a governmental organization, but
19 go on.

20 A. I have no issue with the EPA. I
21 find them to be reputable.

22 (Exhibit No. 11 marked)

23 BY MR. ZELLERS:

24 Q. Deposition Exhibit 11 --

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1 MS. O'DELL: Thank you.
2 BY MR. ZELLERS:
3 Q. -- is from the EPA website, and
4 it sets forth the standards for scientific
5 integrity. Is that right?
6 MS. O'DELL: &Object to the
7 form.
8 A. That's what it looks like.
9 BY MR. ZELLERS:
10 Q. Do you see that the EPA explains
11 that scientific integrity is highly important
12 to insulate the scientific community from
13 things such as bias, falsification, and
14 plagiarism?
15 MS. O'DELL: What page are you
16 reading from?
17 MR. ZELLERS: Page 2.
18 BY MR. ZELLERS:
19 Q. I'm looking at the middle of the
20 page. "Scientific integrity is important
21 because it provides insulation from
22 plagiarism" -- correct?
23 A. That's what it says, yeah.
24 Q. It also provides insulation from

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1 A. Held accountable for what?
2 BY MR. ZELLERS:
3 Q. You have no issue that you, as
4 an expert, need to be free from bias,
5 falsification, and plagiarism in your review
6 analysis and preparation of your report in
7 this matter. Correct?
8 MS. O'DELL: Object to the form.
9 A. I think you're asking me, you
10 know, if I maintain scientific integrity. Is
11 that right? If that's your question, the
12 answer is yes.
13 BY MR. ZELLERS:
14 Q. And the EPA, which you cite and
15 rely on, cites standards for scientific
16 integrity. Correct?
17 A. Yeah.
18 Q. And those standards state that
19 scientific integrity is important because it
20 provides insulation from bias, falsification,
21 and plagiarism. Correct?
22 A. That's what it says.
23 Q. You agree with that?
24 A. Yeah.

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1 research misconduct. Is that right?
2 MS. O'DELL: Object to the form.
3 I don't see where it says "misconduct"
4 on the document. I may be --
5 MR. ZELLERS: Sure.
6 MS. O'DELL: I may be missing
7 it.
8 MR. ZELLERS: Okay. And,
9 actually, I'd rather the witness ask me
10 questions, but I'll try to help you
11 here.
12 BY MR. ZELLERS:
13 Q. "Why is scientific integrity
14 important?"
15 The second bullet point says,
16 "Scientific integrity, along with federal
17 policies on research misconduct" -- it gets
18 to the point where scientists such as
19 yourself can be held accountable. Do you
20 agree?
21 MS. O'DELL: Excuse me. Object
22 to the form, misstates the document.
23 You can answer if you understand the
24 question.

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1 Q. Correct?
2 A. Yeah.
3 Q. All right. Are you familiar
4 with the Office of Research Integrity? And
5 let me hand you a page from their website
6 that we'll mark as Exhibit 12.
7 (Exhibit No. 12 marked)
8 A. No, I am not.
9 BY MR. ZELLERS:
10 Q. You've never heard of the Office
11 of Research Integrity?
12 A. No, I haven't.
13 Q. Are you aware that the federal
14 government has an Office of Research
15 Integrity?
16 A. No.
17 Q. Do you see from Deposition
18 Exhibit 12 that plagiarism is defined as the
19 appropriation of another person's ideas,
20 processes, results, or words without giving
21 appropriate credit?
22 A. Yes.
23 Q. Do you agree with that
24 definition of plagiarism?

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1 A. It seems like a reasonable 2 definition of plagiarism. 3 Q. Are you aware that several 4 paragraphs from your report were copied and 5 pasted from various websites and articles? 6 A. Yes. 7 Q. Can you tell us where in your 8 report you copied and pasted statements from 9 other websites and articles? 10 A. I mean, a good majority of the 11 report was drawn from those sources. 12 Q. It would be wrong for you to 13 simply lift or copy and paste the text from 14 other sources and include it in your report 15 without giving attribution to those sources. 16 Correct? 17 MS. O'DELL: Object to form. 18 A. I did every -- I made every 19 effort to cite where I drew information from. 20 And, Counselor, if you're going to suggest 21 that copying and pasting information into 22 that report, specifically in the appendices, 23 represents plagiarism, that was a collation 24 of the information from which I formed the	Page 90	Page 92 1 different. I'm not talking about 2 paraphrasing. I'm not talking about where 3 you do cite to a source. 4 It would be wrong for you as an 5 expert witness in this case to lift, word for 6 word, text from other articles and other 7 sources and include those in your report. 8 Correct? 9 A. I did not -- 10 MS. O'DELL: Excuse me. Object 11 to the form. 12 A. No. I disagree. 13 BY MR. ZELLERS: 14 Q. It would be appropriate for -- 15 MS. O'DELL: Excuse me, sir. 16 MR. ZELLERS: Sure. 17 MS. O'DELL: If you're not 18 finished, you may finish your answer. 19 A. I wasn't finished. I had to 20 gather information on these chemicals, and I 21 relied upon several sources to do so. The 22 appendices were created by examining those 23 sources, collating that information, which 24 included copying and pasting it in the
1 basis of that report and the opinion. 2 BY MR. ZELLERS: 3 Q. Would it be wrong, in the body 4 of your report, not speaking of the 5 appendices, for you to copy and paste 6 statements from other authors and websites 7 and materials without giving attribution to 8 those sources? 9 MS. O'DELL: Object to the form. 10 A. I don't think so. 11 BY MR. ZELLERS: 12 Q. You think it would be 13 permissible to take quotes from other 14 articles, websites, and sources, include them 15 in the body of your report, and pretend that 16 they are your words? 17 MS. O'DELL: Object to the form. 18 A. I don't believe I did that. I 19 believe that what I did was either paraphrase 20 or cite to a source. And if I have missed a 21 citation, then, you know, it's easily 22 corrected. 23 BY MR. ZELLERS: 24 Q. My question is a little	Page 91	Page 93 1 report. So, no, it's absolutely not 2 inappropriate to do so. 3 BY MR. ZELLERS: 4 Q. I am not speaking of the 5 appendices. I'm speaking of the body of your 6 report where you set forth your opinions. 7 It would be wrong in the body of 8 your report to lift and copy and paste text 9 from other articles or from other sources 10 without giving attribution to those sources. 11 Correct? 12 MS. O'DELL: Object to the form. 13 A. No, I don't believe so. I don't 14 believe I did that. I believe that in some 15 of the tables I recite some of the items from 16 the appendices word for word. So -- 17 MS. O'DELL: Excuse me. Let 18 him -- you may finish. 19 A. Yeah. So let's be very clear 20 about this, Counselor. If you're going to 21 suggest that my report is anything less than 22 ethical and that there's plagiarism or this 23 or that, I was relying upon that information 24 to draw, you know, the conclusions and the

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<p>1 opinions that I drew. 2 BY MR. ZELLERS: 3 Q. So I understand your testimony, 4 you do not believe that it is wrong for you 5 to take, word for word, information -- 6 A. Why don't you show me where that 7 is. 8 MS. O'DELL: Excuse me. Let him 9 finish. 10 BY MR. ZELLERS: 11 Q. Let me finish my question. 12 MS. O'DELL: And then let me 13 object. So you can finish your -- 14 BY MR. ZELLERS: 15 Q. Would it be wrong for you, in 16 the body of your report, to go to other 17 articles or other sources and lift that 18 information word for word and include it in 19 your report without attribution to other 20 sources? Would that be wrong? 21 MS. O'DELL: Object to the form, 22 asked and answered, misstates his prior 23 testimony. You may answer the question 24 as you understand it.</p>	<p>Page 94</p> <p>1 entire paragraph -- second paragraph under 2 Section 4.2 on Page 18 -- is copied and 3 pasted word for word from an article written 4 by Anne Steinemann and published in 5 Environmental Impact Assessment Review, 2008? 6 A. I may have reviewed that and 7 gotten it from there and, you know, didn't do 8 an adequate job of paraphrasing. May I see 9 the article, please? 10 Q. Sure. Because it's your 11 testimony it would be okay if you paraphrased 12 statements from Ms. Steinemann in her paper. 13 Is that right? 14 MS. O'DELL: Object to the form. 15 A. Yes. 16 (Exhibit No. 13 marked) 17 BY MR. ZELLERS: 18 Q. I'm going to hand you what we'll 19 mark as Deposition Exhibit 13. 20 A. Okay. 21 Q. Which is the Steinemann article. 22 Your first sentence of this paragraph starts 23 with, "Regulation of consumer products 24 largely falls under the Consumer Products</p>
<p>1 A. Yeah. I don't believe I did it. 2 If I did, it was an oversight. Okay? And 3 I'll state again -- 4 MS. O'DELL: There's no -- 5 BY MR. ZELLERS: 6 Q. Turn to -- 7 MS. O'DELL: There's no question 8 pending. 9 BY MR. ZELLERS: 10 Q. Turn to Page 18 of your report. 11 Do you see Page 18? 12 A. Yes. 13 Q. Paragraph 2. Are those your 14 words? And I'm sorry. So it's clear, 15 Paragraph 2 underneath Section 4.2, fragrance 16 chemical regulatory review. 17 MS. O'DELL: Just so I'm clear, 18 the paragraph beginning "Regulation of 19 consumer products"? 20 MR. ZELLERS: Yes. 21 BY MR. ZELLERS: 22 Q. Are those your words? 23 A. I believe I typed them, yeah. 24 Q. Are you aware that nearly that</p>	<p>Page 95</p> <p>1 Safety Act." 2 Is that right? 3 A. Yes. 4 Q. Go to Page 2 of the Steinemann 5 article underneath the regulatory analyses, 6 the third paragraph, second sentence, 7 "Regulation of consumer products largely 8 falls under the Consumer Products Safety 9 Act," and I eliminated the statement in 10 parens. 11 That's word for word. Correct? 12 A. No, it's not. 13 Q. What -- other than the omitted 14 paren which states "other than food, drugs 15 cosmetics, tobacco, and pesticides" that -- 16 A. Yeah, those are the same words, 17 that's correct. Without the parens, that's 18 right. 19 Q. Then we go to the second 20 sentence, and go down to the next paragraph 21 in Dr. Steinemann's report, the one that 22 starts "notably." Do you see that? 23 A. Yes. 24 Q. Then it continues, "The CPSA</p>

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<p>1 does not require disclosure of all 2 ingredients in products," and it continues 3 for several more sentences. 4 Those sentences appear, word for 5 word, in your second paragraph on Page 18. 6 Correct?</p> <p>7 MS. O'DELL: Object to the form. 8 A. I believe I paraphrased it. I 9 don't think it's word for word. 10 BY MR. ZELLERS: 11 Q. Well, I don't want to take the 12 time to go through and do a word-for-word 13 analysis. 14 Go to, then, if you will, Page 3 15 of the Steinemann article, and the first 16 sentence on Page 3, "Ingredients can also be 17 exempt from disclosure." 18 You state that sentence as the 19 next sentence in your report. Right? 20 A. Yep. 21 MS. O'DELL: Object to the form. 22 BY MR. ZELLERS: 23 Q. Then if we go to the next 24 paragraph, several sentences in where it</p>	<p>1 Q. Go to Page 27 of your report. 2 Do you see the last full paragraph? 3 A. Yes. 4 Q. Are you aware that the last full 5 paragraph on Page 27 of your report, all but 6 the first sentence was copied and pasted from 7 a Wikipedia entry on mucus membrane? 8 MS. O'DELL: Object to form. 9 A. I believe I paraphrased it. 10 BY MR. ZELLERS: 11 Q. Well, I will let the record 12 speak for itself in terms of doing the 13 word-by-word comparison. I don't believe 14 that you did, but we'll let the record, 15 again, speak for itself. 16 Look at Page -- strike that. 17 (Exhibit No. 14 marked) 18 BY MR. ZELLERS: 19 Q. Look at Exhibit 14, which is the 20 Wikipedia entry or statement on mucous 21 membrane. 22 MS. O'DELL: Is this 14? 23 MR. ZELLERS: Yes, 14. 24</p>
<p>1 says, "Under the FFDCA, fragrance ingredients 2 that qualify," that sentence appears verbatim 3 in your report. Is that right? 4 MS. O'DELL: Object to the form. 5 A. Where is this? 6 BY MR. ZELLERS: 7 Q. So you go to the second 8 paragraph on Page 3 of the Steinemann 9 article. The sentence starts -- and this is 10 about three or four sentences in -- "Under 11 the FFDCA, fragrance ingredients that qualify 12 as trade secrets," that is your last sentence 13 in Paragraph 2 of your report. Is that 14 right? 15 A. Yeah, that's consistent. 16 MS. O'DELL: Object to the form. 17 BY MR. ZELLERS: 18 Q. All right. Have you read the 19 Consumer Product Safety Act, the Federal 20 Hazardous Substances Act, or the Toxic 21 Substances Control Act? 22 A. I did go pull them up on the 23 internet and took a look at them. I didn't 24 read them in total.</p>	<p>1 BY MR. ZELLERS: 2 Q. You are -- and specifically you 3 have lifted verbatim in the second to last 4 paragraph or the last full paragraph on 5 Page 27 the Wikipedia statement as to what a 6 mucous membrane or mucosa is. And I'm 7 looking at the very first page, the 8 introductory paragraph of Exhibit 14. Is 9 that right? 10 MS. O'DELL: Object to form. 11 A. I believe I paraphrased it, as 12 I've said. 13 BY MR. ZELLERS: 14 Q. Well, you start with -- and I'm 15 looking at the second sentence -- "A mucous 16 membrane or mucosa is a membrane," and then 17 you end the paragraph, four or five sentences 18 later, by stating, "prevent bodily tissues 19 from becoming dehydrated." 20 At least those words are the 21 same words. Correct? 22 A. I will take -- 23 MS. O'DELL: Object to the form. 24 A. I will have to take a look at</p>

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1 it. 2 BY MR. ZELLERS: 3 Q. You are aware that Wikipedia is 4 not a peer-reviewed source. Correct? 5 A. I believe that it's reviewed by 6 anyone who wants to, yeah. 7 Q. Anyone can update a Wikipedia 8 entry? 9 A. I believe so, yeah. 10 Q. Go to Page 32 of your report. 11 I'm looking at the second to last full 12 paragraph that starts with "traditionally." 13 Do you see where I'm at? This is in Section 14 4.5. 15 A. Yeah. 16 Q. It would be the second to last 17 full paragraph on Page 32 of your report. 18 Are you aware that that 19 paragraph is taken directly from a website 20 called Interactive Learning Paradigms, 21 Incorporated? 22 A. No. 23 MS. O'DELL: And excuse me. 24 Just -- so you're talking about the	Page 102 1 you have Exhibit 15 in front of you? 2 A. Yes. 3 Q. Do you have your report in front 4 of you, Page 32? 5 A. Yes. 6 Q. Do you see the last paragraph of 7 Deposition Exhibit 15, the website for 8 Interactive Learning Paradigms, Incorporated, 9 that begins, "Traditionally, sensitization 10 has been determined"? 11 Do you see that? 12 A. Yes. 13 Q. Would you agree that that 14 paragraph, excluding the very last sentence 15 that is the citation to the EPA, is exactly 16 the same paragraph as appears in your report 17 on Page 32? 18 MS. O'DELL: Object to the form. 19 A. Yeah, it looks like it. 20 MR. ZELLERS: Let's take a 21 break. Thank you. 22 THE VIDEOGRAPHER: Going off the 23 record, the time is 10:50 a.m. 24 (Recess from 10:50 a.m. to
Page 103 1 sentence -- the paragraph beginning 2 "traditionally"? 3 MR. ZELLERS: Yes. 4 BY MR. ZELLERS: 5 Q. You are unaware of that, Doctor? 6 A. I don't think so. 7 Q. Well, it would be wrong for you 8 to lift statements from other articles or 9 other authors or Wikipedia and include them 10 in your report word for word without 11 attribution. Correct? 12 MS. O'DELL: Object to the form. 13 A. You know, I tried to paraphrase 14 where appropriate. If I missed -- missed 15 something and didn't cite it, it was an 16 oversight. 17 BY MR. ZELLERS: 18 Q. Take a look at Page 15 -- strike 19 that. 20 Take a look, if you will, at 21 Exhibit 15. 22 (Exhibit No. 15 marked) 23 BY MR. ZELLERS: 24 Q. This is the ILPI website. Do	Page 105 1 11:07 a.m.) 2 THE VIDEOGRAPHER: This marks 3 the beginning of Disc 2. Back on the 4 record, the time is 11:07 a.m. 5 BY MR. ZELLERS: 6 Q. Dr. Crowley, your first opinion 7 is that the fragrance chemicals in baby 8 powder and Shower to Shower are not in 9 compliance with governmental and industry 10 standards. Correct? 11 A. Yes. 12 Q. Your second opinion is that the 13 fragrance chemicals in these talcum powder 14 products contribute to the inflammatory 15 properties, toxicity, and potential 16 carcinogenicity of these products. Is that 17 right? 18 A. Yes. 19 Q. Is it your opinion that the 20 fragrance chemicals alone can cause cancers? 21 MS. O'DELL: Objection; form. 22 A. I was not asked to make that 23 consideration. 24

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1 BY MR. ZELLERS:

2 Q. You are not expressing an
3 opinion as to whether or not the fragrance
4 chemicals alone can either cause cancer or
5 increase the risk of cancer. Correct?

6 MS. O'DELL: Object to the form.

7 A. That's -- that's correct.

8 BY MR. ZELLERS:

9 Q. It also -- strike that.

10 You also are not expressing any
11 opinion that the fragrance chemicals alone
12 can cause or increase the risk for ovarian
13 cancer. Correct?

14 A. That's correct.

15 Q. Are you aware of any
16 epidemiology that substantiates the theory
17 that fragrance chemicals in talc can either
18 cause cancer or increase the risk of cancer?

19 MS. O'DELL: Object to the form.

20 A. Yeah. As I cited in my report,
21 there's a number of fragrance chemicals with
22 demonstrated in vitro and in vivo studies
23 that demonstrated a higher risk or, in fact,
24 in which cancer occurred.

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1 MS. O'DELL: Object to the form,
2 asked and answered. You may answer the
3 question.
4 A. No, I did -- I wasn't asked to
5 consider that.

6 BY MR. ZELLERS:

7 Q. You are not rendering any
8 opinion that fragrance chemicals plus talc
9 cause ovarian cancer. Correct? You leave
10 that to other experts?

11 A. That's correct.

12 Q. You are not offering any
13 opinions about the inhalation exposure to
14 fragrance chemicals. Is that right?

15 A. That's correct.

16 Q. You're not providing any
17 opinions relating to asbestos. Correct?

18 A. That's correct.

19 Q. Your opinions in this matter,
20 other than putting them in your report, have
21 you published on them?

22 A. No.

23 Q. What methodology -- strike that.
24 Why haven't you published on

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1 BY MR. ZELLERS:

2 Q. Those studies you cite to --

3 A. Yes.

4 Q. -- are reference -- let me
5 finish.

6 Those studies you cite to are
7 referenced in your report. Is that right?

8 A. Yes.

9 Q. For any individual plaintiff in
10 this litigation, do you know what amount of
11 fragrance chemicals individual plaintiffs
12 were exposed to?

13 MS. O'DELL: Object to the form.

14 A. No, I do not.

15 BY MR. ZELLERS:

16 Q. Did you make any effort to
17 discern any individual plaintiff's level of
18 exposure?

19 A. No. I wasn't asked to consider
20 that.

21 Q. Did you make any effort to
22 discern whether any individual plaintiff was
23 actually exposed to harmful levels of
24 fragrance chemicals?

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1 your opinions that you're expressing in this
2 case?

3 A. I signed a protective order.

4 This is all confidential information.

5 Q. What methodology did you use in
6 reaching your opinions in this case?

7 A. I was given the list of
8 fragrance chemicals. I set about identifying
9 them. The names of the chemicals were in the
10 Thomas Dydek report. That often started by
11 just plugging that into Google or PubChem to
12 see what I could find.

13 After doing that, I would then
14 try to identify a CAS number so I could
15 cross-reference it into various databases and
16 gather the physical and chemical properties,
17 as well as the safety profile, in vitro or in
18 vivo studies, and any published or known
19 pharmacological properties.

20 I would then go to IFRA and CIR
21 websites and look at their -- the information
22 they had on it, the FDA website, in
23 particular the Inactive Ingredient Database.

24 I looked in some of the

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1 journals, specifically Food and Chemical
2 Toxicology, to see what the studies were. I
3 looked at the EFSA website, the European Food
4 Safety Authorities, you know, all the
5 different places that I've identified in my
6 report and gathered as much information as I
7 could on it.

8 Once Appendix A and Appendix B
9 were built, then I started classifying them.
10 How many of them are considered -- are
11 classified as irritants? Which ones are
12 allergens? Which ones are eye irritants?
13 And so forth.

14 I also looked at, you know, the
15 RTECS database, the Registry of Toxic Effects
16 of Chemical Substances, and so forth.

17 There's a tremendous amount of
18 work to identify some of these chemicals
19 because the names given to me, you know,
20 aren't the standard chemical names. So there
21 was a significant effort just to try and
22 figure out what they were.

23 Q. Essentially what you have done
24 in this case is to take the list of fragrance

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1 and to render your opinions.

2 A. I mean, there's books on how you
3 formulate and the steps that you take to
4 gather the information on the materials and
5 chemicals that you're going to use to create
6 a composition and how you go about doing
7 that. So I imagine that it's been published
8 in one way or another.

9 Q. To your knowledge, the
10 methodology that you have used in reviewing
11 the information relating to fragrance
12 chemicals and arriving at your opinions has
13 not been subject to peer review. Correct?

14 MS. O'DELL: Object to the form.

15 A. I'm not sure I understand your
16 question. Look, these are chemicals. Okay?
17 I mean, they happen to be fragrances, but
18 they're really no different than a chemical
19 used to make a food or a pharmaceutical.
20 They're chemicals.

21 When you're doing a safety
22 assessment of them, there's a number of ways
23 to collect and collate that information. I
24 don't think that anything that I did is

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1 chemicals or fragrance ingredients and then
2 Google them or ChemPub them and go to
3 websites, FDA and IFRA and others, to catalog
4 or to list out information about the
5 fragrance chemicals. Is that right?

6 MS. O'DELL: Object to the form.

7 A. That's -- that's generally
8 correct. I also, you know, like I said,
9 looked at the technical literature. I mean,
10 it wasn't just websites, databases. I tried
11 to examine the totality of the evidence for
12 each and every chemical and collate that into
13 a meaningful -- in a meaningful way to
14 examine their properties and to answer the
15 questions that were posed to me.

16 BY MR. ZELLERS:

17 Q. Do you know whether the
18 methodology that you've used, whether that's
19 been published anywhere?

20 A. The methodology that I used to
21 gather the information, whether --

22 Q. Yes.

23 A. -- that's been published?

24 Q. Used to gather the information

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1 different than what a standard formulator
2 would use in putting a product together for
3 examining the safety of a -- of a commercial
4 product.

5 BY MR. ZELLERS:

6 Q. Do you believe the standard for
7 proving causation in the scientific
8 literature is the same as the one that
9 applies in litigation?

10 MS. O'DELL: Object to the form.

11 Are you talking about for a specific
12 disease or --

13 MR. ZELLERS: I'm just asking
14 the questions. If you can, just limit
15 your objection to form.

16 BY MR. ZELLERS:

17 Q. So I'm asking you that question,
18 Doctor. If you can answer it, please do. If
19 you can't, okay.

20 A. Could --

21 MS. O'DELL: I object to the
22 form of the question. It's vague.
23 It's unclear. But if you understand
24 it, you may answer it.

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1 A. I was going to ask him to repeat
2 it, please.

3 BY MR. ZELLERS:

4 Q. Sure. Do you believe the
5 standard for proving causation in the
6 scientific literature is the same as the one
7 that applies in litigation?

8 A. I'm not sure.

9 Q. Are you aware of any publication
10 that links the fragrance chemicals in baby
11 powder and Shower to Shower to ovarian
12 cancer?

13 MS. O'DELL: Object to the form.

14 A. I don't believe I found a source
15 that made that association. However, you
16 know, as I said earlier, a number of these
17 chemicals have demonstrated studies against
18 Chinese hamster ovary cells or in vivo animal
19 studies in which cancers in the ovaries were
20 found.

21 BY MR. ZELLERS:

22 Q. Doctor, you have found no
23 publication that links the fragrance
24 chemicals in baby powder and Shower to Shower

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1 Q. Any others?

2 A. Yes. d-Limonene was found to
3 be cytotoxic against Chinese hamster ovary
4 cells. I'm not sure how to pronounce the
5 name of this author, but it's
6 K-P-O-V-I-E-S-S-I, et al., from 2014.

7 Q. What page of your report?

8 A. Page 22.

9 Q. All right. Any other articles
10 or publications that link the fragrance
11 chemicals or a fragrance chemical that you
12 believe is in baby powder and Shower to
13 Shower to ovarian cancer?

14 A. There's a bunch of them.
15 Page 22, Skatole, cytotoxic against Chinese
16 hamster ovary cells. That was in Reddy,
17 2002.

18 Q. Any others?

19 A. Yes. Styrene, cytogenic DNA
20 damage, DNA inhibition, sister chromatid --

21 THE REPORTER: I'm sorry. Try
22 to slow down for me. I've got to write
23 what you're saying.

24 THE WITNESS: I'm sorry.

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1 and human ovarian cancer. Correct?

2 A. Human ovarian cancer?

3 Q. Yes.

4 MS. O'DELL: Excuse me. Object
5 to the form. You may answer.

6 A. Not humans, no. Animal models,
7 yes.

8 BY MR. ZELLERS:

9 Q. What animal models are you
10 referring to that relate to fragrance
11 chemicals?

12 A. I'm going to refer to my report.

13 Q. Sure.

14 A. So benzaldehyde, sister
15 chromatid exchange, which is a mutation, in
16 Chinese hamster ovary cells. That was
17 published by Galloway in '87.

18 Q. What reference is that?

19 A. Galloway, et al., 1987.

20 Q. You're reading from your report.

21 A. That's correct.

22 Q. What page of your report are you
23 reading from?

24 A. Page 22.

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1 THE REPORTER: That's okay.

2 A. Cytogenic DNA damage, DNA
3 inhibition, sister chromatid exchange, un --

4 BY MR. ZELLERS:

5 Q. And that relates to ovarian
6 cancer. Correct?

7 A. Yes.

8 MS. O'DELL: Please finish,
9 Dr. Crowley.

10 A. Benzyl alcohol, cytogenic in
11 Chinese hamster ovary cells, National

12 Toxicology Program, 1989.

13 Citral, selective oocyte
14 degeneration and impaired fertility in female
15 rats. Toaff, which is spelled T-O-A-F-F,
16 Abramovici, Sporn & Liban, 1979.

17 Valid genotoxic (induction of
18 sister chromatid exchange) in Chinese hamster
19 ovary cells, National Toxicology Program,
20 2003. And same author as before,
21 K-P-O-V-I-E-S-S-I, 2014.

22 Coumarin, sister chromatic
23 exchange in Chinese hamster ovary cells,
24 Galloway, 1987.

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<p>1 BY MR. ZELLERS:</p> <p>2 Q. Are you finished?</p> <p>3 A. No. Ethyl methylphenylglycidate</p> <p>4 sister chromatid exchange and chromosomal</p> <p>5 aberrations in Chinese hamster ovary cells,</p> <p>6 Galloway, 1987.</p> <p>7 European Food Safety Authority,</p> <p>8 same substance. There's substantial evidence</p> <p>9 of a genotoxic potential from the available</p> <p>10 in vitro and in vivo studies.</p> <p>11 Eugenol, sister chromatid</p> <p>12 exchange and chromosomal aberrations in</p> <p>13 Chinese hamster ovary cells, Galloway, 1987.</p> <p>14 Styrax oil, sister chromatid</p> <p>15 exchange in Chinese hamster ovary cells,</p> <p>16 Gulati, Witt, Anderson, Zeiger & Shelby,</p> <p>17 1989.</p> <p>18 para-Cresol, cytogenetic in</p> <p>19 Chinese hamster ovary cells, DNA damage in</p> <p>20 human lymphocytes, morphologic</p> <p>21 transformations in mice, RTECS, the Cosmetic</p> <p>22 Ingredient Review Panel, 2006.</p> <p>23 para-Cresol was considered</p> <p>24 positive for reducing chromosomal aberrations</p>	<p>1 BY MR. ZELLERS:</p> <p>2 Q. Are you familiar with a paradigm</p> <p>3 developed by the National Academy Of</p> <p>4 Sciences, also known as the NRC?</p> <p>5 A. I have heard of the NRC. I'm</p> <p>6 trying to remember what the acronym stands</p> <p>7 for. Would you please enlighten me?</p> <p>8 Q. Let's go step by step.</p> <p>9 (Exhibit No. 16 marked)</p> <p>10 BY MR. ZELLERS:</p> <p>11 Q. Deposition Exhibit 16 is an EPA</p> <p>12 NRC Risk Assessment Paradigm. Is that right?</p> <p>13 MS. O'DELL: If you haven't seen</p> <p>14 this before, Doctor --</p> <p>15 THE WITNESS: I haven't --</p> <p>16 MS. O'DELL: -- feel free to</p> <p>17 take a few minutes and --</p> <p>18 A. I haven't seen this particular</p> <p>19 document before.</p> <p>20 BY MR. ZELLERS:</p> <p>21 Q. Are you generally familiar with</p> <p>22 risk assessment?</p> <p>23 A. Yes.</p> <p>24 Q. Are you aware and do you agree</p>
<p>1 in Chinese hamster ovary cells under both</p> <p>2 activation and non-activation conditions.</p> <p>3 para-Cymene, cytotoxic against</p> <p>4 Chinese hamster ovary cells.</p> <p>5 Q. Are you finished?</p> <p>6 A. Propanedioic acid, diethyl</p> <p>7 ester, tumorigenic in mice following oral</p> <p>8 dosing, RTECS.</p> <p>9 Q. Are you finished?</p> <p>10 A. That's -- that's the baby powder</p> <p>11 product. I'd like to go to Shower to Shower,</p> <p>12 if you'd like.</p> <p>13 Q. Is it all listed in your report?</p> <p>14 A. Yes.</p> <p>15 Q. All right. Let's move on, and</p> <p>16 we'll incorporate, as we have, your report</p> <p>17 into your response.</p> <p>18 You are familiar -- strike that.</p> <p>19 Are you familiar with a human</p> <p>20 health risk assessment?</p> <p>21 MS. O'DELL: Object to the form</p> <p>22 of -- to the preamble to the question.</p> <p>23 A. Yes.</p> <p>24</p>	<p>1 that there's different stages or steps to a</p> <p>2 risk assessment?</p> <p>3 A. Yes.</p> <p>4 Q. Look at the bottom of Page 16.</p> <p>5 A. I only have three pages here.</p> <p>6 Q. I'm sorry. That's a bad</p> <p>7 question. Let me withdraw it.</p> <p>8 Look at the bottom of the first</p> <p>9 page of Deposition Exhibit 16, which sets</p> <p>10 forth the National Academy of Sciences' risk</p> <p>11 assessment steps.</p> <p>12 Do you see that at the bottom of</p> <p>13 the first page of Exhibit 16?</p> <p>14 A. Yes.</p> <p>15 Q. Do you agree that the steps in a</p> <p>16 risk assessment are; No. 1, hazard</p> <p>17 identification; No. 2, dose response</p> <p>18 assessment; No. 3, exposure assessment, and,</p> <p>19 No. 4, risk characterization?</p> <p>20 MS. O'DELL: Objection; form.</p> <p>21 A. That's what it says.</p> <p>22 BY MR. ZELLERS:</p> <p>23 Q. Are you generally familiar with</p> <p>24 these steps of a risk assessment?</p>

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<p>1 A. Yes. 2 Q. All four steps are necessary to 3 complete a full risk assessment. Is that 4 right? 5 MS. O'DELL: Object to the form. 6 A. According to this paradigm and 7 this model. 8 BY MR. ZELLERS: 9 Q. And according to your 10 background, your training, your education. 11 Is that right? 12 MS. O'DELL: Object to form. 13 BY MR. ZELLERS: 14 Q. Or do you have any background 15 training in risk assessment? 16 A. I do have background in it, 17 and -- 18 Q. Do you agree that generally -- 19 MS. O'DELL: Excuse me, sir. I 20 don't think he was finished. 21 A. Yeah. I would have to study 22 this in greater detail to ensure that it's 23 consistent with how I've seen it done. I'm 24 more familiar with the FDA's risk assessment</p>	<p>Page 122</p> <p>1 hazard. I was provided with a list of 2 chemicals and asked two questions. 3 Q. You have not done a dose 4 response assessment in this case for any of 5 the fragrance chemicals in either the talc 6 powder or the Shower to Shower powder. 7 Correct? 8 A. I was unable to do it because I 9 wasn't given, No. 1, the information to know 10 how much of each fragrance chemical was 11 present in the composition, and when we were 12 given that information, there's no units 13 there. 14 More importantly, you know, as I 15 just cited from my report, some of these 16 fragrance chemicals are genotoxic. You don't 17 need to do a dose response relationship for a 18 genotoxic material, because genotoxins you 19 need one molecule for there to be an 20 increased risk, one. 21 Q. You have not done any exposure 22 assessment in this case. Correct? 23 A. That's correct. I was not asked 24 to do so.</p>
<p>1 models. And there's another model called the 2 Muller model that's been used in toxicology 3 and pharmacology. 4 BY MR. ZELLERS: 5 Q. Did you attempt to do a risk 6 assessment analysis in this case? 7 A. I wasn't asked to do a risk 8 assessment. 9 Q. Do you think it would be 10 important in terms of arriving at your 11 opinions in this case to do a risk 12 assessment? 13 MS. O'DELL: Object to the form. 14 A. Not necessarily. 15 BY MR. ZELLERS: 16 Q. All right. You have not done a 17 risk assessment in this case. Correct? 18 MS. O'DELL: Excuse me. Object 19 to the form. 20 A. No, I have not. 21 BY MR. ZELLERS: 22 Q. You identified a potential 23 hazard. Is that right? 24 A. I was not asked to identify a</p>	<p>Page 123</p> <p>1 Q. You have not done a risk 2 characterization or analysis in this case. 3 Correct? 4 A. That's correct. And I wasn't 5 asked to do that. 6 Q. Are you familiar with -- 7 MS. O'DELL: Excuse me. 8 Counsel, with your permission, can I 9 lodge my objection? I was slow off the 10 mark to that question. 11 BY MR. ZELLERS: 12 Q. Are you familiar with the 13 concept of dose response? 14 A. Yes. 15 Q. The science of toxicology is 16 based on the principle that there is a 17 relationship between a toxic reaction and the 18 amount of a substance received. Correct? 19 A. That's only partially correct, 20 Counselor. As I just indicated, genotoxic 21 materials do not -- are not thresholded. 22 They don't have a threshold. One molecule is 23 enough to cause an increased risk. 24 Non-genotoxic carcinogens do</p>

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1 have the dose response relationship.

2 Q. You've not considered dose
3 response in this case. Correct?

4 A. I wasn't asked --

5 MS. O'DELL: Excuse me. Object
6 to the form, misstates his testimony.
7 You may answer the question.

8 BY MR. ZELLERS:

9 Q. Go ahead.

10 A. I was not asked to, and I was
11 unable to based on the information that I was
12 given.

13 Q. Those fragrance chemicals that
14 you believe are capable of a genotoxic
15 response, have you identified those in your
16 report?

17 A. First of all, I don't believe
18 they are. I didn't do the research. I'm
19 simply reporting what I found in the
20 research. Those conclusions were drawn by
21 the authors of those studies. I'm simply
22 reporting that they were found to have valid
23 genotoxic results.

24 Q. What you did is you went out and

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1 because it couldn't be reproduced or the
2 study design is not consistent with
3 established standard."

4 So I certainly took those into
5 consideration as well. So if it was a study
6 that was not considered to be valid, I didn't
7 report it.

8 BY MR. ZELLERS:

9 Q. There is a difference between
10 animal studies and human studies. Correct?

11 A. That's correct.

12 Q. You can't just apply an animal
13 study or results of an animal study to a
14 human study. Correct?

15 MS. O'DELL: Object to the form.

16 A. I don't know how to answer that
17 question. What do you mean by "apply"?

18 BY MR. ZELLERS:

19 Q. I will withdraw the question.

20 Do you agree that all substances
21 can be potentially hazardous if the dose is
22 too high?

23 MS. O'DELL: Object to the form.

24 A. I mean, that's sort of a

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1 you were asked by counsel for plaintiffs to
2 catalog the information relating to these
3 fragrance chemicals. Is that right?

4 MS. O'DELL: Object to the form.

5 A. I reviewed the totality of the
6 evidence on the chemicals.

7 BY MR. ZELLERS:

8 Q. You then have reported that
9 information in your report. Correct?

10 MS. O'DELL: Object to the form.

11 A. Yes.

12 BY MR. ZELLERS:

13 Q. Any genotoxic characteristic of
14 any of the fragrance chemicals would be set
15 forth in the information you've collected in
16 your report. Fair?

17 MS. O'DELL: Object to the form.

18 A. Yeah. If I found a genotoxic
19 result, I would report it unless, of
20 course -- and there were some instances --
21 for example, the European Food Safety
22 Authority was actually quite good about
23 saying, you know, "This result was positive
24 for genotoxicity, but we are dismissing it

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1 hypothetical. What if -- fairytale land. So
2 I suppose, if you have too much water, you
3 could drown, or too much salt, that could
4 cause problems.

5 Generally speaking, poisons are,
6 you know, dose-and-exposure relationship.
7 So, in that context, yes, most materials
8 could be hazardous if too much is consumed or
9 if the exposure is too great.

10 BY MR. ZELLERS:

11 Q. Do you agree that for chemicals
12 and substances there can be multiple routes
13 of exposure?

14 A. I'm not sure what you're asking
15 me. Yes, you know, you can inhale air and
16 you can also have transdermal absorption.

17 Q. You can also have ingestion.

18 Correct?

19 A. Yeah.

20 Q. Those are all different routes
21 of exposure?

22 A. Yes.

23 Q. Is that right?

24 A. I prefer to call them routes of

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1 administration, typically, is the 2 nomenclature used. 3 Q. Do you agree that if a person is 4 exposed to a substance by ingestion, they 5 will absorb a different amount of a substance 6 than if the substance is applied to the skin, 7 a dermal exposure? 8 A. So you're speaking in 9 generalities, and it varies from substance to 10 substance. The bioavailability is, I think, 11 what you're referring to. So you may eat 12 something and only half of it is absorbed 13 into the body, a portion of it may be 14 metabolized in the stomach or not absorbed at 15 all. 16 It would have a different 17 pharmacokinetic profile when absorbed through 18 the skin, perhaps. So route of 19 administration does impact pharmacokinetics 20 and biological activity, including toxicology 21 and pharmacology. 22 Q. Can the route of exposure have 23 an impact on the amount of a substance that 24 is absorbed by the body?	Page 130	Page 132
1 A. Yes. 2 Q. Do you agree that it is not 3 scientifically valid to only identify a 4 hazard and then try to formulate conclusions 5 about the risk of a particular contaminant 6 without going through a full risk assessment? 7 MS. O'DELL: Object to the form. 8 A. Can you repeat the question? 9 BY MR. ZELLERS: 10 Q. Sure. Do you agree that in 11 order to have a scientifically valid opinion 12 with respect to the risk of a particular 13 contaminant, it is important to go through a 14 full risk assessment? 15 A. No. 16 MS. O'DELL: Object to the form. 17 BY MR. ZELLERS: 18 Q. It's not necessary? 19 A. No. 20 Q. It's not necessary to look at 21 dose response in that relationship. Correct? 22 A. As I told you earlier, genotoxic 23 materials do not live under a dose response 24 relationship. If it's been classified as	Page 131	Page 133

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1 that.

2 Q. The risk assessment, one element
3 or part of it, would be to do a dose response
4 assessment. Correct?

5 A. That is often done with new
6 molecular entities and chemicals to establish
7 their safety profile.

8 Q. Another part of a risk
9 assessment would be an exposure assessment.
10 Correct?

11 A. Yes.

12 Q. There then would be a risk
13 characterization. Is that right?

14 MS. O'DELL: Object to the form.

15 A. Yes.

16 BY MR. ZELLERS:

17 Q. All right. You have not done
18 that analysis for the fragrance chemicals
19 identified in the talcum powder in this case.
20 Correct?

21 MS. O'DELL: Objection.

22 A. No. I relied upon the available
23 information for the chemicals from, you know,
24 MSDS sheets and the published studies that

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1 A. I counted. The same way for
2 baby powder. I counted based off of the
3 information disclosed.

4 Q. In Dr. Dydek's report?

5 A. Yeah.

6 MS. O'DELL: Object to the form.

7 BY MR. ZELLERS:

8 Q. Does the list of fragrance
9 chemicals that you relied on indicate the
10 amount of each chemical in baby powder?

11 A. No.

12 Q. Does it indicate the amount of
13 each chemical in baby powder -- strike that.

14 Withdraw.

15 Does it indicate the amount of
16 each chemical in Shower to Shower?

17 A. No.

18 Q. What is the concentration of
19 each of the fragrance chemicals that you have
20 identified in a bottle of baby powder?

21 MS. O'DELL: Object to the form.

22 A. I don't know. I wasn't provided
23 that information.

24

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1 did do those things.

2 BY MR. ZELLERS:

3 Q. In your report, you state that
4 there are 141 fragrance chemicals in baby
5 powder. Is that right?

6 A. Yes.

7 Q. Where did you get that number
8 from?

9 A. I counted the ones that were
10 disclosed to me in the Dydek report, and I
11 noted that some of those fragrances are
12 actually mixtures of chemicals themselves.
13 So, for example, certain gums are actually --
14 or resins are actually crude extracts that
15 are actually a combination. And I think I
16 used the word "at least."

17 Q. You did not do any independent
18 testing of the baby powder to try to
19 determine what fragrance chemicals were
20 included in the powder. Correct?

21 A. No, I did not do any testing.

22 Q. In your report, you say there
23 are 53 fragrance chemicals in Shower to
24 Shower. Where did you get that number from?

1 BY MR. ZELLERS:

2 Q. What is the concentration of
3 each of the fragrance chemicals that you have
4 identified in a bottle of Shower to Shower?

5 A. I don't know. I wasn't provided
6 that information.

7 Q. Can you tell me how much of each
8 fragrance chemical is in one ounce of baby
9 powder?

10 A. No, I cannot.

11 Q. In one ounce of Shower to
12 Shower?

13 A. No, I can't. In part, it would
14 have been nice to have seen where -- in
15 industry standard content uniformity studies.
16 So the fragrance is blended with talcum
17 powder, and it's industry standard to take
18 aliquots of the blend and test them to verify
19 that they're uniformly and homogeneously
20 mixed, but that information wasn't made
21 available to me.

22 Q. Did you ask counsel for that
23 information?

24 A. I did.

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<p>1 Q. Did you do any independent 2 testing to determine the concentration of the 3 fragrance chemicals?</p> <p>4 A. No.</p> <p>5 Q. In what other products are any 6 of these ingredients used? Are you --</p> <p>7 A. I wasn't asked to consider that.</p> <p>8 MS. O'DELL: Excuse me. Excuse 9 me. When you say "ingredients," you're 10 talking about the totality of all the 11 chemicals that are listed in his 12 report, or are you asking just 13 generally are there other products that 14 they're used in?</p> <p>15 MR. ZELLERS: Counsel, I'm more 16 concerned if the witness doesn't 17 understand the question than whether 18 you understand the question. My 19 question --</p> <p>20 MS. O'DELL: I understand that, 21 but I need to understand in order to 22 object and make my record, so --</p> <p>23 BY MR. ZELLERS:</p> <p>24 Q. My question is: Did you attempt</p>	<p>Page 138</p> <p>1 want to complete your answer, Doctor, 2 you are welcome to do that.</p> <p>3 A. Yeah. So it's disclosed in 4 my -- in my report. I reviewed the FDA's 5 Inactive Ingredient Database for each one of 6 these chemicals, and on Page 43, Table 14 7 lists those chemicals that are listed on the 8 Inactive Ingredient Database.</p> <p>9 Those chemicals listed for 10 topical administration -- in other words, to 11 the skin -- and those chemicals that are 12 listed for vaginal administration. According 13 to paragraph -- or Table 14 on Page 43, 14 benzyl alcohol present in baby powder is 15 listed for vaginal administration. That's 16 the only one in baby powder.</p> <p>17 In Shower to Shower, that 18 information is in Table 23 on Page 61, the 19 same type of table with IID listed, topical 20 administration and vaginal administration. 21 In Shower to Shower, propylene glycol and 22 t-butyl hydroquinone are the only two that 23 are in approved products for vaginal 24 administration.</p>
<p>1 to look or make a determination as to in what 2 other products any of these fragrance 3 chemicals are used?</p> <p>4 A. Yes, I did. I looked on the FDA 5 Inactive Ingredients Database.</p> <p>6 Q. Did you make a determination as 7 to in what other products they are used 8 vaginally?</p> <p>9 A. Yes.</p> <p>10 Q. Did you include that in your 11 report?</p> <p>12 A. Yes.</p> <p>13 Q. What fragrance chemicals did you 14 identify that are used vaginally?</p> <p>15 A. I'm going to have to go look at 16 the report, because I don't have that 17 committed to memory, but --</p> <p>18 Q. Well, do you state it or set it 19 forth in the report?</p> <p>20 A. Yes.</p> <p>21 Q. Just tell me the page or where I 22 can look for that notation.</p> <p>23 MS. O'DELL: You -- you may tell 24 him the page, certainly, but if you</p>	<p>Page 139</p> <p>1 BY MR. ZELLERS:</p> <p>2 Q. Do you know when the list of 3 fragrance chemicals that you relied on from 4 Dr. Dydek's report was produced?</p> <p>5 MS. O'DELL: Object to the form.</p> <p>6 A. Do I know when I received it? 7 Are you asking when I got it or --</p> <p>8 BY MR. ZELLERS:</p> <p>9 Q. My question is: Do you know for 10 what period of time that list of fragrance 11 ingredients was for?</p> <p>12 MS. O'DELL: Object to the form.</p> <p>13 A. I'm not sure I understand what 14 you're asking me.</p> <p>15 BY MR. ZELLERS:</p> <p>16 Q. Sure.</p> <p>17 A. Are you asking me do I know what 18 time period that fragrance composition was 19 used in those products?</p> <p>20 Q. Let me try to ask a better 21 question.</p> <p>22 Do you know if the list of 23 fragrance chemicals for the baby powder is 24 the list of current fragrance ingredients?</p>

<p>1 A. No, I -- 2 MS. O'DELL: Objection -- 3 objection to form. You can answer. 4 A. Yeah, I don't know with 5 certainty. We did ask for the list of 6 fragrance chemicals and all change control 7 documents associated with that composition. 8 So the presumption is that the information 9 that we were given is current. 10 As I was finishing this report, 11 we were provided some information that showed 12 a few compositional changes over the years. 13 For example, styrene, I believe, was removed 14 in, I think, 2014. 15 BY MR. ZELLERS: 16 Q. Do you know if the list of 17 fragrance chemicals in Shower to Shower that 18 you relied on is the current list of 19 fragrance chemicals? 20 MS. O'DELL: Object to the form. 21 A. Yeah, same answer. 22 BY MR. ZELLERS: 23 Q. Do you know if the list of 24 fragrance chemicals for either baby powder or</p>	<p>Page 142</p> <p>1 potential harm caused by the fragrance 2 chemicals in the products? 3 A. You know, I would have to review 4 those changes and take that into 5 consideration. To be able to provide an 6 open-ended answer without reviewing the 7 underlying information and what those changes 8 were I think would be inappropriate. So I'd 9 be happy to take that into consideration and 10 be given an opportunity to study it. 11 Q. Let me ask you about your first 12 opinion, and that is that several of the 13 chemicals used in the J&J Consumer Products, 14 Inc., talc products are not in compliance 15 with governmental and industry standards. 16 That's your opinion. Is that right? 17 A. Correct. 18 Q. As part of that opinion, you 19 identify 22 fragrance chemicals in baby 20 powder with a regulatory concern. Is that 21 right? 22 A. Yes. 23 Q. And 20 fragrance chemicals in 24 Shower to Shower with a regulatory concern.</p>
<p>1 Shower to Shower has changed over time? 2 MS. O'DELL: Object to the form, 3 asked and answered. 4 A. I answered that. We were 5 provided with one document that showed a 6 history of changes, and it did show some 7 changes over time. 8 BY MR. ZELLERS: 9 Q. That is the only information you 10 have in terms of how the composition of 11 fragrance chemicals has changed relating to 12 either baby powder or Shower to Shower. Is 13 that correct? 14 A. Yes. 15 MS. O'DELL: Object to the form. 16 BY MR. ZELLERS: 17 Q. Do you know whether the 18 concentration of the fragrance chemicals has 19 changed over time for either baby powder or 20 Shower to Shower? 21 A. I do not know. 22 Q. If the list or concentration of 23 the fragrance chemicals changed over time, 24 would that impact your analysis regarding any</p>	<p>Page 143</p> <p>1 Is that right? 2 A. Yes. 3 Q. You define regulatory concern as 4 seven different categories on Page 18 of your 5 report. Is that right? 6 A. Yes. 7 Q. Is regulatory concern a 8 recognized term in the field of toxicology? 9 MS. O'DELL: Object to the form. 10 A. I mean, toxicology and 11 regulations are two different things, so I 12 think you're sort of confusing two very 13 different subjects, so -- 14 BY MR. ZELLERS: 15 Q. You're the one who is opining 16 that there is regulatory concern with regard 17 to certain of the fragrance chemicals. 18 Correct? 19 A. So, yes, I am summarizing review 20 of the compliance of these particular 21 chemicals. And I'd just like to add that I 22 was provided with some documents where J&J 23 did their own regulatory review of these 24 chemicals, and the words they used were</p>

<p>1 "regulatory concern." So I borrowed that -- 2 I don't think that's plagiarism, but I 3 borrowed the use of those two words to title 4 this section. 5 Q. In the couple of courses that 6 you took on toxicology, do you recall being 7 taught that regulatory concern is a 8 recognized term in that field? 9 MS. O'DELL: Object to the form. 10 A. You're confusing two completely 11 different things. 12 BY MR. ZELLERS: 13 Q. Can you answer my question? 14 A. And I am answering. And, you 15 know, apples and oranges are both fruits, but 16 they have different colors. Your question 17 doesn't make any sense at all. 18 Regulations and toxicology are 19 two different things. 20 Q. Is regulatory concern a 21 recognized term in the field of regulations? 22 MS. O'DELL: Object to the form. 23 A. I suppose you could ask the FDA. 24</p>	<p>Page 146</p> <p>1 Table 6. Do you have Table 6 in front of 2 you? 3 A. I do. Page 18 and 19 and 20. 4 Q. The column to the right, 5 regulatory concern -- in that column, you 6 list the reasons you believe the specific 7 chemicals you list constitute a regulatory 8 concern. Is that right? 9 A. Yes. 10 Q. You did the same thing for 11 Shower to Shower in Table 15? 12 A. Yes. 13 Q. Is that right? 14 A. Yes. 15 Q. The reasons that you include in 16 this column are the same seven categories 17 that you include in your definition of 18 regulatory concern from Page 18 of your 19 report. Is that right? 20 A. Yes. 21 Q. You only -- strike that. 22 In Table 6 and Table 15, you 23 only identify three specific statutory and/or 24 regulatory sources in the regulatory concern</p> <p>Page 148</p>
<p>1 BY MR. ZELLERS: 2 Q. You list all the fragrance 3 chemicals in baby powder that you believe 4 present a regulatory concern in Table 6 of 5 your report. Is that right? 6 A. Yes, as they've been defined 7 within the report. 8 Q. You list all the chemicals that 9 you believe present a regulatory concern 10 relating to Shower to Shower in Table 15 of 11 your report. Is that right? 12 A. I believe so, yes. 13 Q. If a fragrance chemical is 14 included in Table 6 or Table 15, does that 15 mean it causes cancer? 16 A. No. You know, again, you're 17 confusing regulations with toxicology. So 18 the first question relates to do regulatory 19 bodies, trade groups, say you can use these 20 things. Okay? Those regulations are often 21 based on toxicology, but you seem to be 22 confused on how they're applied and how this 23 information is to be understood. 24 Q. Take a look, if you will, at</p>	<p>Page 147</p> <p>1 column. Is that right? 2 MS. O'DELL: Object to the form. 3 A. I'd have to go check that. 4 BY MR. ZELLERS: 5 Q. You list CFR Title 21, CIR, 6 which is Cosmetic Ingredient Review, and 7 IFRA, International Fragrance Association. 8 Is that right? 9 MS. O'DELL: Object to the form. 10 A. I think, actually, there's four. 11 The Code of Federal Regulations, IFRA, CIR, 12 and the EU Annex, which I think is from -- is 13 that from European Food Safety -- you know, I 14 didn't -- I didn't count it up. Like I said, 15 I tried to look at all the different sources, 16 and these were the primary regulatory bodies 17 that make (inaudible) -- 18 Q. The other -- 19 THE REPORTER: I'm sorry. The 20 regulatory bodies that? 21 THE WITNESS: That make those 22 regulations. 23 BY MR. ZELLERS: 24 Q. The other four categories of</p> <p>Page 149</p>

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<p>1 potential regulatory concern that come from 2 your report, Page 18, those are not listed as 3 reasons for regulatory concern in the table. 4 Is that right?</p> <p>5 MS. O'DELL: Object to the form.</p> <p>6 A. I'm sorry. I'm not sure I 7 follow your question.</p> <p>8 BY MR. ZELLERS:</p> <p>9 Q. And let me ask a better 10 question.</p> <p>11 The other four categories that 12 you include in the regulatory concern column 13 do not cite or reference any regulations or 14 databases. Is that right?</p> <p>15 A. Well, for example, not permitted 16 for cosmetic use. Copper chlorophyll, it is 17 an approved colorant by FDA, but it's not 18 allowed for use in cosmetics. So I didn't 19 cite to the specific source of that 20 information here in this table, but if you go 21 to the Appendix A, you can click a hyperlink 22 and it will take you right to the citation in 23 the Code of Federal Regulations.</p> <p>24 Q. What I'm trying to identify are</p>	<p>1 finish his answer.</p> <p>2 BY MR. ZELLERS:</p> <p>3 Q. You can finish your answer, but 4 I need you to just answer my questions or 5 we'll be here forever.</p> <p>6 My question simply was: Did you 7 use the Code of Federal Regulations? Finish 8 your answer, and then I'll ask another 9 question, but I want to try to move this 10 along.</p> <p>11 MS. O'DELL: He's answering the 12 question. Answer it fully.</p> <p>13 A. I've got all day, so we -- we 14 can be here as long as we need to.</p> <p>15 MS. O'DELL: We're going to be 16 here for seven hours on the record, but 17 keep -- you may answer his question.</p> <p>18 A. So all these things are 19 considered by a scientist when creating a 20 product, and that includes looking at what 21 the government says is allowed to be used, 22 how it can be used, what kind of products it 23 can be used in, how much it can be used for 24 which given route of administration. And</p>
<p>1 just the regulations or databases that you're 2 relying on with respect to regulatory 3 concern. So, No. 1, you looked at Code of 4 Federal Regulations, Title 21. Is that 5 right?</p> <p>6 A. Yeah.</p> <p>7 Q. And one of the reasons that you 8 list for various fragrance chemicals is that 9 the chemical is not listed in Code of Federal 10 Regulations, Title 21. Is that right?</p> <p>11 A. That's right. And the reason 12 for that is when formulation scientists, 13 whether they be a cosmetic chemist, a food 14 scientist, or a pharmaceutical scientist, is 15 going to create a product, use those that are 16 approved. And one of the first places you 17 look is the Code of Federal Regulations on 18 how they can be used, what they can be used 19 in, and how much they can be used for a given 20 route of administration. Now you start 21 looking at some of these other regulatory 22 bodies for specifications. So this --</p> <p>23 Q. Doctor --</p> <p>24 MS. O'DELL: Excuse me. Let him</p>	<p>1 then you go and start looking below that at 2 the regulatory bodies in the world of 3 cosmetics. That includes CIR and IFRA -- or 4 the Food Chemicals Codex if it's something 5 used in foods, or the pharmacopeias, if 6 there's a standard for that.</p> <p>7 So, you know, when I'm hired to 8 help create a product, these are all things 9 that we consider when we build it.</p> <p>10 MR. ZELLERS: Move to strike as 11 nonresponsive.</p> <p>12 BY MR. ZELLERS:</p> <p>13 Q. To what section of CFR Title 21 14 are you referring to?</p> <p>15 A. I'm sorry? You're asking me 16 which section?</p> <p>17 Q. Yes. Which -- CFR Title 21 is 18 big. Right?</p> <p>19 A. Yeah.</p> <p>20 Q. What section did you look at in 21 terms of your analysis in this case in 22 determining that the absence of a listing of 23 a fragrance chemical in CFR Title 21 is a 24 regulatory concern?</p>

<p>1 A. So if you go to the government's 2 website, you can pull up Part 21 of the Code 3 of Federal Regulations, and you can type in 4 something and search for it. So I searched 5 for the whole thing.</p> <p>6 Generally speaking, GRAS-listed 7 chemicals are -- have a little monograph 8 there or a section or code. I looked in the 9 entirety of Title 21, which covers food, 10 drugs, and cosmetics.</p> <p>11 Q. Do all fragrance chemicals in 12 the United States need to be listed in Code 13 of Federal Regulations, Title 21?</p> <p>14 A. No.</p> <p>15 MS. O'DELL: Object to the form.</p> <p>16 BY MR. ZELLERS:</p> <p>17 Q. Why does not being listed in CFR 18 Title 21 present a regulatory concern?</p> <p>19 A. It means the FDA has not 20 reviewed the data on it.</p> <p>21 Q. One way or the other. Correct?</p> <p>22 A. Correct.</p> <p>23 Q. Look at -- strike that. 24 You also identify as a</p>	<p>Page 154</p> <p>1 ingredients may be excluded from evaluation 2 by the CIR expert panel if their safety is 3 being determined by the Research Institute 4 for Fragrance Materials?</p> <p>5 A. Yes.</p> <p>6 Q. So the CIR may not even review 7 fragrance chemicals if RIFM --</p> <p>8 A. And REXPAN have done that.</p> <p>9 Q. Have done that. Is that right?</p> <p>10 A. Yeah, that's correct.</p> <p>11 Q. Why, then, is -- if a fragrance 12 chemical is not listed in CIR, why does that 13 present a regulatory concern?</p> <p>14 A. Because some of the chemicals 15 are not fragrances.</p> <p>16 Q. Do you identify which chemicals 17 are not fragrances in your report?</p> <p>18 A. Yes.</p> <p>19 Q. Take a look at IFRA. You list 20 as an additional reason in Table 6 for 21 regulatory concern if there is no IFRA -- and 22 IFRA is International Fragrance Association. 23 Is that right?</p> <p>24 MS. O'DELL: Object to the form.</p>
<p>1 regulatory concern if a fragrance chemical is 2 not listed by CIR, the Cosmetic Ingredient 3 Review. Is that right?</p> <p>4 A. Yes.</p> <p>5 Q. Are you familiar with CIR's 6 review procedures?</p> <p>7 A. I have read about them, yeah. 8 (Exhibit No. 17 marked)</p> <p>9 BY MR. ZELLERS:</p> <p>10 Q. Deposition Exhibit 17. Are 11 these the Cosmetic Ingredient Review 12 procedures that you reviewed in connection 13 with your analysis of this matter?</p> <p>14 MS. O'DELL: Object to form.</p> <p>15 A. I don't know.</p> <p>16 BY MR. ZELLERS:</p> <p>17 Q. Are you familiar with these 18 procedures?</p> <p>19 A. I believe I've read a few 20 articles that have been published about the 21 CIR QRA system and so forth, but I don't know 22 that I've reviewed this specific document, to 23 be candid with you.</p> <p>24 Q. Do you agree that fragrance</p>	<p>Page 155</p> <p>1 A. International -- I have the name 2 of IFRA in my report. I think you got it 3 right. International Fragrance -- is it 4 Research Association?</p> <p>5 BY MR. ZELLERS:</p> <p>6 Q. Well, whether it's International 7 Fragrance Research Association or 8 International Fragrance Association, we both 9 know what --</p> <p>10 A. IFRA is, yes.</p> <p>11 Q. -- IFRA is. Is that right?</p> <p>12 A. I think -- I think we can agree 13 upon that, yeah.</p> <p>14 Q. IFRA makes usage standards for 15 fragrance chemicals. Is that right?</p> <p>16 A. I think they also make purity 17 standards as well.</p> <p>18 Q. Is that a yes?</p> <p>19 A. Yes. Sorry about that.</p> <p>20 Q. It's okay. 21 (Exhibit No. 18 marked)</p> <p>22 BY MR. ZELLERS:</p> <p>23 Q. Deposition Exhibit 18.</p> <p>24 Deposition Exhibit 18, if you look at the</p>

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<p>1 second paragraph, are those the standards for 2 the IFRA expert panel?</p> <p>3 MS. O'DELL: I just object to 4 this exhibit to the degree it seems to 5 be an incomplete copy of whatever is 6 being presented.</p> <p>7 BY MR. ZELLERS:</p> <p>8 Q. The top of the document, 9 Exhibit 18, says, "about the standards - 10 IFRA, International Fragrance Association," 11 and at the bottom there's a citation to the 12 IFRA website. Is that right?</p> <p>13 A. Yes.</p> <p>14 MS. O'DELL: I stand on my 15 objection of the document itself.</p> <p>16 BY MR. ZELLERS:</p> <p>17 Q. In order for IFRA -- let me 18 withdraw that.</p> <p>19 To make usage standards, there 20 is an independent expert panel that performs 21 a safety assessment for and as part of IFRA. 22 Correct?</p> <p>23 A. Yeah, that's correct.</p> <p>24 Q. And if the safety assessment</p>	<p>Page 158</p> <p>1 And if you need to read the document 2 he's referring to, feel free to do 3 that.</p> <p>4 A. It says -- reading Item No. 3, 5 it says, "if the safety assessment does not 6 support the current use, the panel instructs 7 IFRA to issue a standard."</p> <p>8 If you're asking me about that, 9 then that's what it says. That's how they do 10 it.</p> <p>11 BY MR. ZELLERS:</p> <p>12 Q. So in your report, when you list 13 "No IFRA standard" next to an ingredient, 14 that actually means that IFRA has neither 15 restricted nor banned the chemical. Correct?</p> <p>16 A. Not necessarily. They have -- 17 it appeared to me that they have published 18 standards on purity, providing specifications 19 and usage levels, regardless of whether it's 20 restricted or not. They all have -- all the 21 fragrance chemicals that I examined have some 22 sort of usage level.</p> <p>23 Q. Looking at Deposition 24 Exhibit 18 --</p>
<p>Page 159</p> <p>1 does not support the current use of the 2 chemical, the panel instructs IFRA to issue a 3 standard either restricting or banning a 4 material. Is that correct?</p> <p>5 A. That's what it says.</p> <p>6 Q. So that means that if the safety 7 assessment does support the current use of a 8 chemical, IFRA does not issue a standard. 9 Correct?</p> <p>10 MS. O'DELL: Object to the form.</p> <p>11 A. I'm sorry. Can you repeat the 12 question?</p> <p>13 BY MR. ZELLERS:</p> <p>14 Q. Sure.</p> <p>15 A. It's a little confusing.</p> <p>16 Q. We started this day today by my 17 telling you not to answer a question you 18 didn't understand.</p> <p>19 A. Yeah.</p> <p>20 Q. Do you agree that if the safety 21 assessment by the expert panel supports the 22 current use of a chemical, IFRA does not 23 issue a standard? Correct?</p> <p>24 MS. O'DELL: Object to the form.</p>	<p>Page 161</p> <p>1 A. Yeah.</p> <p>2 Q. -- this appears to be from the 3 IFRA website. Correct?</p> <p>4 A. Yeah.</p> <p>5 Q. This describes how the expert 6 panel is used. Is that right?</p> <p>7 MS. O'DELL: Objection.</p> <p>8 A. Yes.</p> <p>9 BY MR. ZELLERS:</p> <p>10 Q. The expert panel is made up of 11 renowned independent experts in the fields of 12 dermatology, toxicology, pathology, and 13 environmental sciences. Is that right?</p> <p>14 MS. O'DELL: Object to form.</p> <p>15 A. That's what it says.</p> <p>16 BY MR. ZELLERS:</p> <p>17 Q. Their role is to evaluate the 18 data on a fragrance ingredient to see if it 19 supports the current use level to make sure 20 that there are no risks for the consumer. In 21 cases where the safety assessment does not 22 support the current use, the panel then 23 instructs IFRA to issue a standard either 24 restricting or banning a material. Did I</p>

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1 read that correctly? 2 A. I believe so. 3 Q. And that is your understanding 4 of how the expert panel is used with respect 5 to the IFRA standards. 6 A. That's -- 7 Q. Is that correct? 8 A. Yes. 9 Q. I'm going to ask you about some 10 of the chemicals that you identify in 11 Tables 6 and 15 as a regulatory concern. 12 No. 1, balsam Peru. Do you see 13 that? 14 A. Yes. 15 Q. Myroxylon pereirae oil, or 16 balsam Peru, was on a list of ingredients 17 that you reviewed. Is that right? 18 A. Yes. 19 Q. That is one of the ingredient -- 20 one of the ingredients that you say is not in 21 regulatory compliance. Is that right? 22 A. Yes. 23 Q. You claim that IFRA prohibits 24 its use as a fragrance. Is that right?	Page 162 1 conjunction with other materials. Is that 2 right? 3 A. Yes. 4 Q. So P means chemicals should not 5 be used as a fragrance ingredient. Correct? 6 A. Yes. 7 Q. R means that IFRA has set a 8 limit as to how much of an ingredient should 9 be used. Is that right? 10 A. Yes. 11 Q. Turn to 163, which is on Page 9 12 of Deposition Exhibit 19. Do you see that? 13 A. No. There's ten pages here, and 14 they're numbered 1 through 10. 15 Q. Go to Page 9. 16 A. Oh. Okay. 17 Q. Entry 163 lists Peru balsam 18 crude as prohibited. Is that right? 19 A. Yes. 20 Q. The next line, Entry 164, it 21 lists Peru balsam extracts and distillates as 22 restricted. Is that right? 23 A. Yes. 24 Q. Restricted means that IFRA has
Page 163 1 A. That's what I found. 2 Q. Take a look at the Index of IFRA 3 Standards, which we will mark as Deposition 4 Exhibit 19. 5 (Exhibit No. 19 marked) 6 BY MR. ZELLERS: 7 Q. Are you familiar, generally, 8 with these standards? 9 A. Yes. 10 Q. The IFRA recommendations are 11 grouped into three categories; P for 12 prohibited, R for restricted, and S for 13 specified. Is that right? 14 A. Yes. 15 Q. Prohibited is material should 16 not be used as a fragrance ingredient. Is 17 that right? 18 A. That's what it says, yes. 19 Q. R, the use of the material 20 should be limited quantitatively? 21 A. Yes. 22 Q. S for specified, the material 23 should only be used if it meets certain 24 purity criteria or if it is used in	Page 163 1 set a level for safe use. Correct? 2 A. Restricted means the material 3 should be limited quantitatively. That's the 4 argument. You've read that to me, and that's 5 right there on your own document. 6 Q. Exactly. So there is a limit in 7 terms of what a level would be for safe use. 8 Correct? 9 A. You're adding words to the 10 definition of what R means. It says, "The 11 use of the material should be limited 12 quantitatively." I don't hear the words or 13 see the words "safe use" there. So you're 14 mischaracterizing what R means. 15 Q. R means that up to a certain 16 limit, it is acceptable to use the chemical 17 according to IFRA? 18 A. That's correct. 19 Q. All right. Do you agree or do 20 you know if balsam Peru oil refers to the 21 extract or distillate? 22 MS. O'DELL: Object to the form. 23 BY MR. ZELLERS: 24 Q. And let me withdraw that. Let

<p>1 me ask a better question.</p> <p>2 Balsam Peru oil refers to the 3 extract or distillate. Is that right?</p> <p>4 A. They both have the same CAS 5 number. Interesting. I want to go to my 6 report and look and see what I wrote, if you 7 don't mind, and that's going to take me a 8 moment to get there. Let me pull it up on 9 the computer. That would be faster.</p> <p>10 Q. Well, here. I can help you, I 11 think. Let me give you a document, and if 12 you need to look at something else, you can 13 look at something else.</p> <p>14 MS. O'DELL: Yeah. Feel free to 15 keep --</p> <p>16 THE WITNESS: I'm going to, 17 yeah.</p> <p>18 MS. O'DELL: Keep reviewing what 19 you'd like to review.</p> <p>20 A. I will tell you what I relied 21 upon.</p> <p>22 BY MR. ZELLERS:</p> <p>23 Q. Well, my question isn't what you 24 relied upon. My question is: Do you agree</p>	<p>Page 166</p> <p>1 A. Yes.</p> <p>2 Q. The ingredient that you 3 reference in your report is Myroxylon 4 pereirae oil or balsam Peru oil. Correct?</p> <p>5 A. Yep.</p> <p>6 Q. That is listed by IFRA in its 7 standards as a Peru balsam extract and 8 distillate. Is that right?</p> <p>9 A. Yes.</p> <p>10 Q. If we look at the IFRA standard, 11 Exhibit 19, and we go back to Page 9 of 10, 12 Entry 164, Peru balsam extract and distillate 13 is a restricted but not prohibited item. Is 14 that right?</p> <p>15 A. That's what it says.</p> <p>16 Q. You do not know the level or 17 amount or concentration of Peru balsam 18 extract and distillate in the baby powder or 19 Shower to Shower powder. Is that correct?</p> <p>20 A. I do not --</p> <p>21 MS. O'DELL: Object to the form.</p> <p>22 A. I do not know the amount.</p> <p>23 BY MR. ZELLERS:</p> <p>24 Q. Take a look at Table 6. You</p>
<p>1 that the substance that the fragrance 2 chemical that you identified is not 3 prohibited by IFRA?</p> <p>4 MS. O'DELL: Object to the form.</p> <p>5 BY MR. ZELLERS:</p> <p>6 Q. And I think I can make it easy 7 for you.</p> <p>8 A. So the source I relied upon said 9 both resins, essential oils, and that was 10 TSCA.</p> <p>11 (Exhibit No. 20 marked)</p> <p>12 BY MR. ZELLERS:</p> <p>13 Q. Deposition Exhibit 20 --</p> <p>14 MS. O'DELL: Are you referring 15 to a particular page in your report?</p> <p>16 A. It's on Page 152.</p> <p>17 BY MR. ZELLERS:</p> <p>18 Q. Deposition Exhibit 20 is the 19 IFRA standard --</p> <p>20 A. And that is -- I did look at 21 that, yeah.</p> <p>22 Q. Deposition Exhibit 20 is the 23 IFRA standard for Peru balsam extracts and 24 distillates. Is that right?</p>	<p>Page 167</p> <p>1 list a fragrance chemical benzene, ethenyl-.</p> <p>2 A. Uh-huh.</p> <p>3 Q. Is that "yes"?</p> <p>4 A. Yes.</p> <p>5 Q. You claim in your report, 6 Table 6, that benzene, ethenyl- is not 7 permitted for flavor or fragrance use. Is 8 that right?</p> <p>9 A. That's correct.</p> <p>10 Q. What is that opinion based on?</p> <p>11 A. FDA recently delisted it.</p> <p>12 Q. Isn't it true the FDA only 13 removed it from its list of approved 14 flavorings because companies stopped using it 15 as a flavoring, but it is not banned as a 16 fragrance?</p> <p>17 MS. O'DELL: Object to the form.</p> <p>18 A. To the best of my knowledge -- I 19 mean, I read the same, probably, report that 20 you did when FDA removed it. I don't believe 21 that it's allowed to be used as a fragrance.</p> <p>22 I also want to go back to the 23 Peru balsam. I pulled up the IFRA standard 24 that I looked at, and it was described as</p>

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1 Peru balsam crude, is listed as prohibited,
2 and the synonyms are the same my -- how do
3 you say it? Myroxylon pereirae?

4 BY MR. ZELLERS:

5 Q. That's absolutely not true, is
6 it?

7 A. I'm looking at it right here.

8 Q. All right. Then let's mark as
9 Deposition Exhibit --

10 A. It's from the 42nd amendment.

11 Q. And it's your testimony under
12 oath that Peru balsam crude is the same as
13 Myroxylon pereirae oil? Is that your
14 testimony under oath?

15 A. No. That's what I'm telling you
16 I drew the conclusion from. I relied upon
17 that.

18 Q. And what you know is that Peru
19 balsam crude is not the ingredient that is in
20 the baby powder or Shower to Shower powder.
21 Correct?

22 MS. O'DELL: Object to the form.

23 A. I don't know that.

24

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1 crude is the same exact CAS number as the
2 oil. Do you see that? So do you now
3 understand how I drew my conclusion?

4 BY MR. ZELLERS:

5 Q. I'm not -- yes. I'm not -- all
6 I care about is that we now have clarified
7 that the fragrance chemical in the baby
8 powder and Shower to Shower powder is the
9 Peru balsam extract and distillate. Correct?

10 MS. O'DELL: Object to the form.

11 A. I'll take your word for it.

12 BY MR. ZELLERS:

13 Q. There is a --

14 MS. O'DELL: Object to the form.

15 BY MR. ZELLERS:

16 Q. There is a separate substance,
17 which is the Peru balsam crude, which is
18 described in IFRA standard that we've marked
19 as Exhibit 21, and that is the prohibited
20 substance. Correct?

21 A. Yeah, and they're both listed
22 Myroxylon pereirae Klotsch. I mean, those
23 three words appear on both. They have the
24 same CAS number. So if what is being used in

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1 BY MR. ZELLERS:

2 Q. Let me help you.

3 A. Let me -- and let me point you

4 to what I'm looking at, because it also
5 describes it exactly as it was described in
6 what I was given, and it says it's
7 prohibited. Balsam oil Peru -- balsam Peru,
8 Myroxylon pereirae balsam Peru oil.

9 (Exhibit No. 21 marked)

10 BY MR. ZELLERS:

11 Q. Okay. Deposition Exhibit 21 is
12 the IFRA standard for Peru balsam crude. Is
13 that right?

14 A. Yes.

15 Q. Peru balsam crude is -- they
16 give a synonym of exudation of Myroxylon
17 pereirae Klotsch. Is that right?

18 A. Yeah, that's what it says right
19 there.

20 Q. Exudation is different than a
21 extract and distillate. Correct?

22 MS. O'DELL: Object to the form.

23 A. Yeah, so let me just point one
24 thing out to you. The CAS number of the

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1 the baby powder is the restricted material
2 instead of the prohibited material, then I'll
3 be happy to update my report.

4 Q. Take a look, then -- so let's go
5 back to my question about benzene, ethenyl-
6 from your report at Table 6, Page 18, and
7 specifically look at Exhibit --

8 MS. O'DELL: Would you mind just
9 saying that chemical again, because I
10 missed it?

11 MR. ZELLERS: Sure. Benzene,
12 ethenyl-, E-T-H-Y --

13 MS. O'DELL: I got it.

14 MR. ZELLERS: -- or maybe
15 E-N-Y-L.

16 MS. O'DELL: Thank you.
17 (Exhibit No. 22 marked)

18 BY MR. ZELLERS:

19 Q. Deposition Exhibit 22, this is
20 the FDA's announcement as to the reason that
21 it was removing benzene, ethenyl- from its
22 list of food additives. Is that right?

23 A. That's what it says, yeah.

24 Q. If you --

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<p>1 A. Why don't we call it styrene. 2 It's a little bit easier to pronounce. 3 Q. If we go to the second page of 4 Exhibit 22, the first paragraph, the reason 5 the FDA gives for removing styrene as a food 6 additive is, "In response to a separate food 7 additive petition from the Styrene 8 Information and Research Center, the FDA is 9 granting the petition by amending its food 10 additive regulations to no longer allow for 11 the use of styrene as a synthetic flavoring 12 substance and adjuvant because industry has 13 abandoned this use." 14 Is that right? 15 A. I believe that you faithfully 16 read that. 17 Q. Okay. This statement says 18 nothing about banning its use as a fragrance. 19 Is that right? 20 A. That's correct. 21 Q. All right. Take a look at your 22 report and your reference to diethyl 23 phthalate. You identified that as a 24 fragrance chemical with a regulatory concern.</p>	<p>Page 174</p> <p>1 fragrance ingredient that is included on the 2 transparency list is included in the RIFM 3 safety assessment program? 4 A. I haven't -- 5 MS. O'DELL: Object to form. 6 A. Yeah. I haven't examined the 7 transparency list and checked to see if RIFM 8 has done a safety assessment on it. So I 9 cannot opine or answer your question. 10 BY MR. ZELLERS: 11 Q. If RIFM has done a safety 12 assessment on diethyl phthalate, then it 13 would be a fragrance. Correct? 14 MS. O'DELL: Object to the form. 15 A. No. 16 BY MR. ZELLERS: 17 Q. Does RIFM -- well, let me 18 withdraw that. 19 You list as a reference an 20 article on the genotoxicity of phthalate 21 esters. Is that right? 22 A. Which one are you referring to? 23 Q. The Al-Saleh, A-L, hyphen, 24 S-A-L-E-H article.</p>
<p>1 Is that right? And I'm looking at Pages 46 2 and 47 of your report, Table 15. 3 A. It's not a fragrance chemical. 4 Yeah, it's listed there. 5 Q. Diethyl phthalate is not a 6 fragrance. Is that right? 7 A. That's correct. 8 Q. For that reason, there is no 9 IFRA standard. Is that right? 10 A. That would probably be why the 11 IFRA folks wouldn't create a standard for it. 12 Q. All right. Diethyl phthalate is 13 listed on the IFRA transparency list. Is 14 that right? 15 A. I am not sure. I'd have to 16 check that. 17 Q. Do you agree that each fragrance 18 ingredient that is included on the 19 transparency list is included in the RIFM 20 safety assessment program? 21 MS. O'DELL: Object to form. 22 A. I'm sorry. Repeat the question. 23 BY MR. ZELLERS: 24 Q. Sure. Do you agree that each</p>	<p>Page 175</p> <p>1 MS. O'DELL: Are you referring 2 to a particular page in the report? 3 MR. ZELLERS: I will. Yeah, 4 Page 66. 5 MS. O'DELL: Okay. Thank you. 6 Page 66 in the report? 7 THE WITNESS: Yes. It's the 8 first reference. 9 MS. O'DELL: Okay. 10 BY MR. ZELLERS: 11 Q. You're generally familiar with 12 the paper. Correct? 13 A. Yeah. I read -- read and 14 reviewed it. 15 (Exhibit No. 23 marked) 16 Q. Take a look -- is Deposition 17 Exhibit 23 that article that you reference in 18 your report. 19 A. I believe so. Yeah. 20 Q. Look at the first page in the 21 left column under introduction. Do you see 22 at the very bottom, the last full sentence, 23 "PAEs, most commonly diethyl phthalate (DEP), 24 are also used as solvents and fixatives in</p>

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<p>1 fragrant products such as perfumes, 2 cosmetics, and personal care products"? 3 Did I read that correctly? 4 A. Where were you? I -- 5 Q. I'm sorry. 6 A. Yeah. 7 Q. I thought we were together. 8 A. Yeah. 9 Q. Exhibit 23. 10 A. Yeah. 11 Q. Introduction on the right-hand 12 side of the first page. 13 A. Yeah. 14 Q. The very last sentence. Do you 15 need me to read it again or -- 16 A. No. 17 Q. -- did I read that correctly? 18 A. Yeah, I believe that you used it 19 faithfully. 20 Q. The authors in this article 21 indicate that diethyl phthalate is a 22 fragrance. Correct? 23 A. No, they do not. 24 Q. Tell me how I'm misreading so --</p>	<p>Page 178</p> <p>1 sentence, "The oversight of the U.S. Food and 2 Drug Administration" -- 3 A. I'm sorry. Where are you? 4 Q. Page 2. 5 A. Yeah. 6 Q. Exhibit 23. 7 A. Yeah. 8 Q. Second sentence, "The 9 oversight" -- 10 A. On the left column? 11 Q. Yes, on the left column. 12 A. First paragraph? Okay. "The 13 U.S. Food and Drug Administration" -- okay. 14 Q. "The oversights of the U.S. Food 15 and Drug Administration (FDA) claim that DEP 16 does not pose a risk to human health." 17 Did I read that correctly? 18 A. I think so. 19 Q. Going down and skipping one 20 sentence, but the next sentence states, "The 21 Cosmetic Ingredient Review (CIR) expert 22 panel, an industry-sponsored organization 23 that regularly reviews the safety of 24 cosmetics supported the FDA claim."</p>
<p>1 A. It's a solvent. 2 Q. Let's look again at the article 3 that you cited for support. Exhibit 23, last 4 sentence under introduction on the first 5 page, "PAEs, most commonly diethyl phthalate, 6 or DEP, are also used as solvents and 7 fixatives in fragrant products such as 8 perfumes, cosmetics, and personal care 9 products." 10 Did I read it correctly? 11 A. Yes. 12 Q. And is that your understanding? 13 A. Yes. It's a solvent, and a 14 solvent and a fragrance are two different 15 things. So phthalate esters, PAEs, and 16 diethyl phthalate do not have a fragrant odor 17 associated with them. They are solvents for 18 the fragrances. 19 Q. They are used in personal care 20 products. Is that right? 21 A. That's what it says, yeah. 22 Q. According to the article that 23 you have cited -- and I'm looking at the next 24 page of the introduction, the second</p>	<p>Page 179</p> <p>1 Did I read that correctly? 2 A. Yes. 3 MS. O'DELL: Object to the form 4 to the extent you left out a portion of 5 that paragraph, but -- 6 MR. ZELLERS: What did I 7 leave -- I left out the cite to the 8 website. Is that right? 9 MS. O'DELL: No. Actually, you 10 left out a sentence, but, you know, 11 keep going. 12 MR. ZELLERS: I don't believe I 13 left out anything material. 14 BY MR. ZELLERS: 15 Q. The next sentence, "The CIR 16 panel reaffirmed the safe use of DEP, DMP, 17 and DBP in cosmetics in 2005." 18 Is that right? 19 MS. O'DELL: Object to the form. 20 A. Yeah, that's what it says. 21 BY MR. ZELLERS: 22 Q. Okay. Going to the next 23 paragraph, "The Scientific Committee on 24 Cosmetics Products and Non-Food Products,</p>

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1 however, did not recommend restrictions on 2 the use of DEP and DMP in cosmetics." 3 Is that right? 4 MS. O'DELL: Objection; form. 5 A. That's what it says. And let's 6 just get something sorted out, because you 7 can read this to me and cite all these 8 regulatory bodies. Diethyl phthalate is not 9 approved for vaginal administration, nor did 10 I find, you know, any safety studies done by 11 any of those bodies that demonstrated that 12 DEP is safe for administration to the vagina. 13 So, you know, earlier you talked 14 about risk assessments. It seems to me you 15 want to ignore route of administration and 16 exposure. These are all for cosmetic use, 17 which is topical to the skin. This speaks 18 nothing to vaginal administration. 19 MR. ZELLERS: Move to strike as 20 nonresponsive. 21 BY MR. ZELLERS: 22 Q. What evidence are you relying on 23 to say that this chemical, diethyl phthalate, 24 causes or increases the risk of ovarian	Page 182	1 induced sister chromatid exchanges." Okay? 2 "And the NTP program also stated" -- and this 3 is a quote -- "there was equivocal evidence 4 of carcinogenic activity of diethyl phthalate 5 in male and female mice based on increases -- 6 increased incidences of hepatocellular 7 neoplasms, primarily adenomas," so -- 8 MR. ZELLERS: Move to strike as 9 nonresponsive. 10 A. You asked me about human. 11 Right? 12 BY MR. ZELLERS: 13 Q. Yes. 14 A. That's the basis for -- from 15 which the information I relied upon, so -- 16 you can pick human, but there's animal data 17 that suggests this is a problem. 18 Q. Just to be clear -- 19 MS. O'DELL: Excuse me, sir. 20 Have you not -- if you're finished, 21 fine, but if you're not finished, you 22 may finish your answer. 23 BY MR. ZELLERS: 24 Q. Just to be clear, and so we have	Page 184
1 cancer in humans? 2 MS. O'DELL: Object to the form. 3 A. Let me go to my report. 4 BY MR. ZELLERS: 5 Q. Well, did you -- and you heard 6 my question, in humans. Correct? I don't 7 need you to read your list of animal studies 8 again. 9 MS. O'DELL: He can read 10 whatever he'd like to in response to 11 your question, Counsel. You know that. 12 So you've asked him a question. It's 13 pending. He's going to respond to it. 14 MR. ZELLERS: And he needs to 15 respond to it. That's my question. 16 MS. O'DELL: You may not like 17 his response, but he's free to respond 18 to it, so -- 19 A. RTECS demonstrate -- you know, 20 stated -- not me, RTECS -- "Diethyl esters 21 can cause reproductive and developmental 22 toxicity. The NTP program found that in 23 cultured Chinese hamster ovary cells, both 24 diethyl phthalate and dimethyl phthalate	Page 183	1 a clear record, you are referencing animal 2 studies. Correct? 3 A. Yeah. 4 Q. My question is: Are you aware 5 of any human studies that demonstrate or 6 provide data that diethyl phthalate causes 7 ovarian cancer in humans? 8 A. No, I'm not. And, you know, as 9 I was saying, there's also not any studies 10 demonstrating the safety in vaginal 11 administration. 12 Q. Let me ask you about a couple 13 more, and then we'll take a break. 14 A. Okay. 15 Q. Citrus Medica Limonum, Pages 18 16 and 19, Table 6. Do you see that? 17 A. There's Citrus Medica Limonum, 18 lemon peel oil, yeah. 19 Q. Yes. And you list that as a 20 fragrance with a regulatory concern. Is that 21 right? 22 A. Yes. 23 Q. You also list this as a 24 fragrance chemical as one with IFRA critical	Page 185

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1 effects. Is that right? 2 MS. O'DELL: Object to the form. 3 BY MR. ZELLERS: 4 Q. On Page 11 -- I'm sorry. 5 Page 37, Table 11. 6 A. Yeah, phototoxicity. 7 Q. Citrus Medica Limonum is lemon 8 peel oil. Is that right? 9 A. Yes, that's my understanding. 10 Q. Citrus Medica Limonum is listed 11 on the IFRA transparency list. Correct? 12 A. I would have to check it. 13 Q. We discussed before that CIR 14 does not evaluate fragrances. Is that right? 15 MS. O'DELL: Object to the form. 16 A. They do in some cases, but they 17 don't always. That's my understanding. 18 BY MR. ZELLERS: 19 Q. Would you agree that the absence 20 of an evaluation by CIR is not a regulatory 21 concern? 22 A. So, I mean, let's be clear about 23 this. When companies engage me to help them 24 build products, they don't want me to take	Page 186 1 BY MR. ZELLERS: 2 Q. Therefore, the absence of an 3 evaluation by CIR, that fact that there is 4 not an evaluation by CIR, is not a regulatory 5 concern in and of itself. Correct? 6 MS. O'DELL: Object to the form. 7 A. That's a generalization. So 8 diethyl phthalate, again, not a fragrance, 9 there is a CIR on it. Right? Okay. You 10 just pointed to the balsam Peru. That's a 11 fragrance. Did CIR have something to say 12 about that? 13 So the absence of something from 14 CIR doesn't mean that, you know -- I forgot 15 how you asked your question. 16 BY MR. ZELLERS: 17 Q. That's all right. The absence 18 may or may not be a regulatory concern? Can 19 we agree on that? 20 A. I guess it depends on who -- 21 MS. O'DELL: Objection; form. 22 A. -- on whose product it is. 23 BY MR. ZELLERS: 24 Q. Why would phototoxicity have
Page 187 1 any unnecessary risks. Right? 2 So, ideally, you use excipients 3 and active ingredients that are listed by the 4 FDA, have a CIR monograph or safety study, 5 you know, are listed in the Food Chemical 6 Codex, have a full -- published in a 7 peer-reviewed journal safety study. 8 So more often than not, the 9 generally-accepted standard is to go use 10 chemicals that meet all those criteria. So 11 there's risk associated with using things 12 that don't. 13 MR. ZELLERS: Move to strike as 14 nonresponsive. 15 BY MR. ZELLERS: 16 Q. Try, if you can, to answer my 17 question. 18 CIR, the Cosmetic Ingredient 19 Review, does not evaluate fragrances. 20 Correct? 21 MS. O'DELL: Object to the form, 22 asked and answered. 23 A. Yeah. I answered that 24 previously and said not always.	Page 189 1 anything to do with peroneal exposure? 2 A. Well, I personally don't sun 3 bathe in the nude, but I suppose some people 4 do. But sunlight can enter through windows. 5 I get your point, taken. 6 MS. O'DELL: Hey, Mike, we've 7 been going about -- Michael, excuse 8 me -- we've been going about an hour 9 and 45 minutes, which I think is 10 gracious of -- 11 MR. ZELLERS: If you could give 12 me five minutes. I just have one -- I 13 mean, and if you have to take a break 14 now, then okay. 15 MS. O'DELL: I just don't want 16 to continue this on -- it's quite a 17 long time we've been going. If you've 18 got five minutes, please finish. 19 MR. ZELLERS: Yeah, let's try to 20 finish this section and decide what 21 we're going to do. 22 MS. O'DELL: But 12:45, an hour 23 and 45 minutes in, it's quite a long 24 time.

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<p>1 MR. ZELLERS: Understood. 2 BY MR. ZELLERS: 3 Q. Methyl Hydrogenated Rosinate, 4 you list that as a fragrance chemical with a 5 regulatory concern. Is that right? 6 A. It's not a fragrance chemical. 7 It's a chemical. 8 Q. So it's your opinion that Methyl 9 Hydrogenated Rosinate is not a fragrance. Is 10 that right? 11 A. That's correct. 12 Q. Would you agree that Methyl 13 Hydrogenated Rosinate is listed on the IFRA 14 transparency list? 15 A. I would have to check. 16 Q. Do you agree that each fragrance 17 ingredient that is included on the IFRA 18 transparency list is included in the RIFM 19 safety assessment program? 20 MS. O'DELL: Object to form. 21 A. I think you asked that of me -- 22 BY MR. ZELLERS: 23 Q. I did of another chemical -- 24 another ingredient.</p>	<p>Page 190</p> <p>1 THE VIDEOGRAPHER: Going off the 2 record, the time is 12:47 p.m. 3 (Recess from 12:47 p.m. to 4 1:55 p.m.) 5 THE VIDEOGRAPHER: This marks 6 the beginning of Disc 3. Back on the 7 record, the time is 1:55 p.m. 8 BY MR. ZELLERS: 9 Q. Dr. Crowley, your second opinion 10 is that the fragrance chemicals in baby 11 powder and Shower to Shower contribute to the 12 inflammatory properties, toxicity, and 13 potential carcinogenicity of these products. 14 Is that right? 15 A. Yes. 16 Q. In your report, you state that 17 35 of the fragrance chemicals in baby powder 18 have a safety/toxicology concern. Correct? 19 A. 35? 20 Q. Yes. Page 11. 21 A. 34. 22 Q. And 12 of the fragrance 23 chemicals in Shower to Shower have a 24 safety/toxicology concern. Is that right?</p>
<p>1 A. Right. I'm sorry. I thought it 2 was open-ended. You know, like I said, I 3 haven't done that cross-reference, so I would 4 have to check that. 5 Q. And the same set of questions 6 with respect to the CIR not evaluating 7 fragrances and not having an evaluation by 8 CIR is not a regulatory concern, you'd give 9 me all the same answers again? 10 A. Pretty much, yeah. 11 MS. O'DELL: Object to the form. 12 A. It depends on who is willing to 13 take on that risk. 14 BY MR. ZELLERS: 15 Q. Last question. Not having an 16 IFRA standard means that IFRA has neither 17 restricted nor banned the chemical. Correct? 18 MS. O'DELL: Object to the form. 19 A. Well, it could also mean they 20 haven't done one, that they haven't done a 21 safety assessment. 22 MR. ZELLERS: Let's take a 23 break. 24 THE WITNESS: Okay.</p>	<p>Page 191</p> <p>1 A. Yes. 2 Q. You define safety/toxicology 3 concern as any fragrance chemical that is 4 listed on the Registry of Toxic Effects of 5 Chemical Substances, or the RTECS list, or 6 has safety in use concerns. Is that right? 7 MS. O'DELL: Object to the form. 8 A. I think I've got a little bit 9 broader definition than that. It's really I 10 considered the totality of the evidence, so 11 certainly RTECS or other toxic, you know, 12 reports from the literature. 13 BY MR. ZELLERS: 14 Q. You list the fragrance chemicals 15 in baby powder, Table 7, that you believe 16 have a safety/toxicology concern. Is that 17 right? 18 A. Well, I don't believe -- I'm 19 reporting work that someone else has done. 20 Q. Right. 21 A. Right. 22 Q. As we established earlier, you 23 personally did not do the review and 24 analysis. You've gone out and you've googled</p>

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1 it or you've PubChem'd it to collect that
2 information?

3 A. Yeah.

4 MS. O'DELL: Object to the form.
5 Misstates his methodology.

6 A. I gathered the information from
7 a number of sources.

8 BY MR. ZELLERS:

9 Q. Is safety/toxicology concern a
10 recognized term in the field of toxicology?

11 A. I mean, it's a term of art, I
12 think, that, you know, adequately describes
13 what I was asked to do.

14 Q. I asked you earlier what
15 methodology you followed. The methodology
16 you followed for your second opinion is the
17 methodology you described for us earlier.
18 Correct?

19 A. Yes.

20 Q. You are not rendering an opinion
21 that if a fragrance chemical is included in
22 either Table 7 or Table 16 of your report,
23 that that means it causes cancer in humans.
24 Correct?

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1 That's a different question than you
2 asked before. You're welcome to answer
3 it.

4 A. Not in humans, but we have
5 in vitro studies and animal studies.

6 BY MR. ZELLERS:

7 Q. Is there any epidemiology
8 substantiating the theory that any of the
9 fragrance chemicals used in baby powder or
10 Shower to Shower cause cancer in humans?

11 MS. O'DELL: Object to the form.

12 A. I think that's the same question
13 you just asked, so it's the same answer.

14 BY MR. ZELLERS:

15 Q. No. Correct?

16 MS. O'DELL: Object to the form.

17 A. No, that's not my answer. Not
18 in humans. There are animal and in vitro

19 studies.

20 BY MR. ZELLERS:

21 Q. You are not aware of any
22 epidemiologic studies that establish that any
23 of the fragrance ingredients that you've
24 listed out cause cancer in humans. Correct?

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1 MS. O'DELL: Object to the form.

2 A. That's not necessarily true.

3 BY MR. ZELLERS:

4 Q. That's not --

5 A. I mean, this isn't a yes or no
6 question. As I understand your question, a
7 number of these chemicals have validated
8 studies that they are carcinogens.

9 Q. What epidemiologic studies in
10 humans substantiate the theory that the
11 fragrance chemicals included in Table 7 and
12 Table 16 cause ovarian cancer?

13 A. Well, I read to you some studies
14 previously. You just rephrased your question
15 to human studies and ovarian cancer. You
16 know, your question prior to that was not
17 specific to ovarian. It was just cancer.
18 Limonene is an IARC potential carcinogen.
19 You know, we've talked about styrene.
20 Q. And I'm sorry to interrupt you.

21 My question is: Are you aware of any
22 epidemiologic studies that associate those
23 fragrances to ovarian cancer in humans?

24 MS. O'DELL: Object to the form.

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1 MS. O'DELL: Object to the form.
2 And if you need to, you're welcome to
3 look at the real-time if you need to
4 look at the question.

5 A. Okay. So that was -- your last
6 question was not specific to ovarian cancer.
7 You said cancer in humans. So I'd like to
8 answer that.

9 Four chemicals in the baby
10 powder have been identified by the
11 International Agency for Research on Cancer
12 as potential carcinogens. Benzene, ethenyl-,
13 also known as styrene, has been implicated as
14 a reproductive toxicant, neurotoxicant, and
15 has been demonstrated to be a carcinogen both
16 in vivo and in vitro.

17 BY MR. ZELLERS:

18 Q. Is that a human study?

19 A. I would have to check the
20 underlying studies.

21 The National Toxicology Program
22 considers styrene to be reasonably
23 anticipated to be a human carcinogen. EPA
24 considers para-Cresol to be possibly

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1 carcinogenic. 2 IARC has also stated that 3 coumarin, eugenol, and d-Limonene are not 4 classifiable as to their carcinogenicity. 5 Q. We -- 6 A. The -- 7 Q. And I'm sorry. You're referring 8 to IARC and to its various analyses. Is that 9 correct? 10 A. That's correct. 11 Q. And I'm going to ask you about 12 that in a bit. 13 A. Okay. 14 Q. All right. 15 A. And I haven't answered your 16 question with respect to Shower to Shower, 17 but there's also similar verbiage, as you're 18 well aware, with respect to Shower to Shower. 19 The chemicals there include benzophenone, 20 which is an IARC Group 2B, coumarin and 21 eugenol are not classifiable, and musk ketone 22 has been suspected of being a carcinogen. It 23 has been classified as a Category 3 24 carcinogen by SCHER, which is the European	Page 198	Page 200 1 products present a health risk for women that 2 use the products? And by "products," I'm 3 including baby powder and Shower to Shower. 4 Is that right? 5 A. Yeah. I believe that perineal 6 application of the talc products is 7 associated with a higher risk of cancer. 8 Q. You have -- 9 A. And I believe that the fragrance 10 chemicals, as they are so called by Johnson & 11 Johnson -- that's not my choice of words, but 12 they're chemicals -- contribute to that. 13 Q. You have not done a full human 14 health risk assessment, correct, as we 15 discussed earlier today? 16 A. I -- 17 MS. O'DELL: Object to form. 18 A. I was unable to do a risk 19 assessment because I was never provided with 20 the composition of the fragrances. So, in 21 order to do that, you need that information. 22 It was asked for, and it was never provided. 23 BY MR. ZELLERS: 24 Q. You have not been able to do a
1 folks. 2 Q. To be clear -- and I understand 3 this is a different question, but there are 4 no epidemiologic studies which substantiate 5 the theory that the fragrance chemicals that 6 you include in either Table 7 or Table 16 7 cause or increase the risk of ovarian cancer 8 in humans. Correct? 9 MS. O'DELL: Object to form. 10 A. I would have to check that, but, 11 you know, I wasn't asked to consider that, 12 so -- 13 BY MR. ZELLERS: 14 Q. At least as you sit here, you 15 are not aware of any. Correct? 16 A. I am not aware of an 17 epidemiological study substantiating the 18 causation of ovarian cancer from the 19 so-called fragrance chemicals. Let's just 20 call them chemicals, because not all of them 21 are fragrances. 22 Q. You believe that the use of the 23 chemicals, including fragrance chemicals, 24 that you've listed in Tables 7 and 16 in the	Page 199	Page 201 1 dose response analysis. Correct? 2 MS. O'DELL: Object to the form. 3 A. Again, I couldn't do it because 4 I didn't have the information from J&J, I 5 suppose, to enable doing that. 6 BY MR. ZELLERS: 7 Q. What dose of the chemicals 8 listed in Table 7 and 16 does a woman receive 9 from one application of baby powder in her 10 perineal region? 11 A. It's unknown to me. That 12 information was requested and not provided. 13 Q. If I asked you what dose there 14 would be for two applications or five or any 15 number, it -- 16 A. I couldn't answer. 17 MS. O'DELL: Object to the form. 18 BY MR. ZELLERS: 19 Q. Do you have any information or 20 are you able to tell me the cumulative dose 21 that a woman would receive if she used baby 22 powder once a day for a year? 23 MS. O'DELL: Object to the form. 24 A. I don't have the information to

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1 make that judgment.
2 BY MR. ZELLERS:
3 Q. If she used it once a day for
4 five years or ten years?
5 MS. O'DELL: Object to the form.
6 A. Same answer.
7 BY MR. ZELLERS:
8 Q. Are you familiar with the
9 standards released by the Globally Harmonized
10 System of Classification and Labeling of
11 Chemicals, or GHS?
12 A. Yes.
13 Q. You rely on the GHS standards in
14 your report. Is that right?
15 A. Yes.
16 Q. It's true, is it not, that for
17 carcinogens, the GHS does not require a
18 hazard statement regarding an ingredient if
19 that ingredient makes up less than
20 0.1 percent of the entire product?
21 MS. O'DELL: Object to form.
22 A. I'd have to check the GHS
23 standards on that.
24

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1 human health if the ingredient represents
2 less than 0.1 percent of the total product
3 other than the genotoxicity issue we talked
4 about earlier?
5 MS. O'DELL: Object to the form.
6 A. Okay. So, as we talked about
7 earlier, genotoxins don't have a threshold.
8 Right? They are -- I'd have to go look at
9 other known carcinogens and what the -- what
10 the -- that are thresholded to answer that
11 question. So it's so open-ended, I couldn't
12 answer without reviewing the literature.
13 BY MR. ZELLERS:
14 Q. One of -- strike that.
15 We talked about exposure and
16 exposure assessments earlier today. Is that
17 right?
18 A. Yes.
19 Q. You've not done an exposure
20 assessment in this case. Right?
21 A. Right. I couldn't because I
22 didn't have the information.
23 Q. Have you ever evaluated a
24 vaginal product?

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1 BY MR. ZELLERS:
2 Q. Take a look at Deposition
3 Exhibit 24.
4 (Exhibit No. 24 marked)
5 BY MR. ZELLERS:
6 Q. Exhibit 24 are the GHS standards
7 of classification and labeling of chemicals.
8 Is that right?
9 A. It's labeled GHS Info Sheet
10 No. 7 on carcinogenicity.
11 Q. All right. If you go to Table 2
12 on Page 2 of Exhibit 24, it provides the
13 cut-off values or concentration limits that
14 trigger the classification of mixtures.
15 A. Okay.
16 Q. Do you see that?
17 A. Yes.
18 Q. And for both Category 1 and
19 Category 2 carcinogens, the cut-off is
20 greater than -- equal to or greater than
21 0.1 percent. Is that right?
22 A. That's what it says.
23 Q. Do you have any science that
24 ingredients can have a critical effect on

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1 A. I've developed vaginal products.
2 There's a product called Crinone. It's
3 commercially available. It's a vaginal cream
4 containing progesterone. It's administered
5 to women to prevent them from going into
6 preterm labor.
7 I've also developed vaginal
8 bacteria -- vaginosis and fungal vaginosis
9 products.
10 Q. When did -- which products?
11 A. So the company that makes
12 Thiola, Mission -- I, for God's sake, cannot
13 think of the name of that product right now.
14 It's escaping me. But they have a bacterial
15 vaginosis product that I helped formulate.
16 Q. And you --
17 A. We also --
18 Q. Go ahead and finish, please.
19 A. Yeah. There's also a company
20 called Columbia Laboratories. They've been
21 bought and sold I don't know how many times.
22 They're the makers of Crinone.
23 We also looked at other products
24 for them based on the, you know, Crinone drug

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1 delivery system. 2 Q. With which company were you 3 with? 4 A. I was with Mission Pharmacal and 5 PharmaForm. 6 Q. PharmaForm is the company you 7 had a disagreement with. Is that right? 8 A. Yeah. 9 Q. What, generally, was the 10 disagreement? 11 A. I was an owner. We sold it. 12 Part of the sale was they wanted us to stay 13 and run it, and there was an employment 14 agreement with -- associated with the sale 15 where they would pay out some money over 16 time. So, after a couple of years, they 17 didn't want to pay. 18 Q. In order for a fragrance 19 chemical or a chemical to get from the 20 peroneal region to the ovaries, they have to 21 get past a number of other structures. Is 22 that right? 23 MS. O'DELL: Object to the form. 24 A. I -- I will defer to the other	Page 206 1 A. I would. 2 Q. -- in terms of that? 3 A. Yeah. 4 THE REPORTER: Try to let him 5 finish his question for me, please. 6 BY MR. ZELLERS: 7 Q. Do you know whether or not the 8 cervix is more or less sensitive than the 9 ovaries to the impact of foreign particles? 10 MS. O'DELL: Object to the form. 11 A. I do not know. 12 BY MR. ZELLERS: 13 Q. You're expressing no opinions 14 and have not considered inhalation exposure. 15 Correct? 16 A. I am not -- 17 MS. O'DELL: Object to the form. 18 A. Yeah, I am not opining on 19 inhalation. 20 BY MR. ZELLERS: 21 Q. In Section 3.9 of your report, 22 you identify a number of components or 23 ingredients for which IREF -- strike that -- 24 IFRA has developed an exposure limit. Is
Page 207 1 experts to opine on that matter. 2 BY MR. ZELLERS: 3 Q. The female reproductive system 4 has a number of defense mechanisms that 5 prevent most foreign particles from getting 6 from the peroneal region to the ovaries. 7 MS. O'DELL: Object -- 8 BY MR. ZELLERS: 9 Q. Is that your understanding? 10 MS. O'DELL: Object to the form. 11 BY MR. ZELLERS: 12 Q. Or do you defer to other experts 13 on that? 14 A. I think I'll defer to other 15 experts there. 16 Q. Have you done any testing to 17 quantify the difference between the dose 18 applied to the peroneal region and the dose 19 that would reach the ovaries, assuming that 20 baby powder or Shower to Shower powder can 21 reach the ovaries? 22 A. No, I have not. 23 Q. You would defer to other 24 experts --	Page 209 1 that right? 2 A. Which page? Table 13 on 3 Page 41? 4 Q. Yes. 5 A. Yeah, some of these are older 6 standards that -- you know, they've -- IFRA's 7 has moved to this QRA. So some of them have 8 been replaced by QRAs, but these are -- some 9 of these are historical. 10 Q. Looking at Page 39, the 11 restriction means that IFRA has recommended 12 that exposure to the ingredient be limited to 13 a specific dose or amount. Is that right? 14 A. Category 5 restriction is 15 defined in my report, yeah. 16 Q. Is that correct? 17 A. Yeah. I mean, there's a 18 percentage there that you're not to exceed. 19 So that's the limitation. 20 Q. Do you have any opinion that the 21 amount of these ingredients in baby powder or 22 Shower to Shower exceed the IFRA 23 recommendations? 24 A. I wasn't able to tell because

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1 I've never been provided the composition,
2 so --
3 Q. In their recommendations, does
4 IFRA say that any of these ingredients
5 contribute to ovarian cancer if they exceed
6 the exposure limit?
7 A. I don't believe IFRA stated
8 that.
9 Q. You referred to the RTECS
10 database. Is that right? And I'm looking at
11 your report, Page 21.
12 A. Yes.
13 Q. What does RTECS stand for?
14 A. The Registry of Toxic Effects of
15 Chemical Substances.
16 Q. Do you know who maintains the
17 RTECS database?
18 A. It was initially maintained by
19 the Center for Disease Control, and I believe
20 it's been sold or outlicensed to other
21 companies.
22 Q. There's now a third party
23 contractor that --
24 A. Yes.

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1 A. That's correct.
2 Q. Food additives are listed on
3 RTECS. Is that right?
4 A. Yes.
5 Q. It's your opinion that fragrance
6 chemicals and chemicals in the talc products
7 contribute to the potential carcinogenicity
8 of the products. Is that right?
9 A. That's correct. Several of --
10 several of the fragrance chemicals are
11 co-carcinogenic, which means they were found
12 to, you know, promote tumors in animals when
13 co-administered with a known carcinogen.
14 Q. Do you agree that it's possible
15 that an ingredient can cause or contribute to
16 the development of one type of cancer but not
17 to another type of cancer?
18 A. Yeah, that's a --
19 MS. O'DELL: Object to the form.
20 A. That's a true statement.
21 BY MR. ZELLERS:
22 Q. Do you agree that it's possible
23 that an ingredient can cause or contribute to
24 the development of cancer or a cancer in an

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1 Q. -- maintains the RTECS database?
2 A. Yes.
3 Q. Are you familiar with NIOSH, the
4 National Institute for Occupational Safety
5 and Health?
6 A. Yes.
7 Q. Are you aware that NIOSH on its
8 website states that it cannot attest to the
9 accuracy of RTECS?
10 A. No, I wasn't aware of that.
11 Q. Does being on RTECS mean that a
chemical is -- strike that.
12 Being listed on RTECS does not
mean that a chemical is harmful. Correct?
13 A. Not necessarily. I mean,
14 there's a set of circumstances where it could
15 be and other circumstances it may not be.
16 Q. Being listed on the RTECS
17 database just means that toxicological data
18 that's been published about the ingredient?
19 A. Yes.
20 Q. Prescription and
non-prescription drugs are listed on RTECS.
21 Correct?

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1 animal but not in humans?
2 A. Yes.
3 Q. Smoking is -- strike that.
4 Smoking is associated with lung
5 cancer. Is that right? If you know.
6 A. Yes.
7 Q. Smoking has not been found to be
8 associated with malignant melanoma. Do you
9 agree?
10 MS. O'DELL: If you know. Don't
11 guess.
12 A. I don't know. My dad has
13 multiple myeloma, and -- and he was a smoker,
14 but I don't know the etiology of -- well, did
15 you say malignant myeloma or --
16 BY MR. ZELLERS:
17 Q. Malignant melanoma.
18 A. Yeah. I don't know if there's
19 an established connection between smoking and
20 that.
21 Q. You're not an expert in cancer.
22 Correct?
23 A. I would not consider myself to
24 be an expert in cancer.

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1 Q. You are not an expert in ovarian
2 cancer. Correct?

3 A. I am not an expert in ovarian
4 cancer.

5 Q. Do you agree that fragrances are
6 generally broken down quickly in the body?

7 MS. O'DELL: Object to the form.

8 A. I don't know that I can agree to
9 a general statement like that. I would have
10 to examine the route of administration. So
11 whether they're applied to the skin or if
12 they're swallowed, as we discussed earlier,
13 the kinetics of how they're metabolized,
14 distributed, and eliminated are a function of
15 those things.

16 BY MR. ZELLERS:

17 Q. Those are all important
18 components. Correct?

19 A. Yes.

20 Q. And you have not done an
21 analysis of that type in this case. Correct?

22 A. That's correct.

23 Q. Do you agree that the primary
24 effects of exposure to fragrance chemicals

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1 A. Yeah. I think I answered that I
2 would take that on a case-by-case basis.
3 There could be chronic effects, especially
4 with respect to sensitizers.

5 BY MR. ZELLERS:

6 Q. You have not done that type of
7 analysis at least with respect to any
8 potential relationship between the fragrance
9 chemicals or chemicals you've identified in
10 baby powder or Shower to Shower and ovarian
11 cancer. Correct?

12 MS. O'DELL: Objection to form.

13 A. Well, several of them did have
14 published chronic dosing studies, and I
15 certainly looked at those. No, I have not
16 done a deep-dive analysis on that.

17 BY MR. ZELLERS:

18 Q. What, if anything, does
19 irritation have to do with the development of
20 ovarian cancer?

21 A. Irritation causes an
22 inflammatory response. Inflammatory
23 responses are associated with a higher risk
24 of developing cancers, and specific --

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1 are acute, like headache or skin irritation?

2 MS. O'DELL: Object to the form.

3 A. Again, it's a general statement.
4 You know, my son is allergic to certain
5 fragrance chemicals, and so you can have an
6 allergic response. Right? I think you
7 mentioned irritation and what else?

8 BY MR. ZELLERS:

9 Q. Do you agree that the primary
10 effects of exposure to fragrance chemicals
11 are acute, like headaches or skin irritation?

12 MS. O'DELL: Object to the form.

13 A. You know, I --

14 BY MR. ZELLERS:

15 Q. Or do you defer on that?

16 A. I think I would do it on a
17 case-by-case basis. I would look at each
18 fragrance chemical and do what I did here.
19 You know, there could be chronic effects from
20 repeat administration. So, no, I wouldn't
21 characterize them as only acute.

22 Q. My question was "are primarily
23 acute."

24 MS. O'DELL: Object to the form.

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1 Q. That's a general statement.

2 Correct?

3 A. It is a general statement. But
4 also, with respect to the vagina, insults to
5 the vagina do, in fact, generate certain
6 proteins that are part of the inflammatory
7 response, and those have been positively
8 linked with higher incidences of cancers in
9 the reproduction -- female reproductive
10 organs.

11 Q. Let me go back to my original
12 question. You are not aware of any
13 epidemiologic studies that associate the
14 fragrance chemicals or the chemicals that you
15 identified in Shower to Shower or baby powder
16 with an increased risk of ovarian cancer.

17 Correct?

18 MS. O'DELL: Object to form.

19 BY MR. ZELLERS:

20 Q. In humans.

21 MS. O'DELL: Object to form.

22 A. I mean, you keep tagging on the
23 "in human" part of it. I mean, we have
24 animal studies that show toxicity issues with

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1 cells in animal models, like Chinese hamster
2 ovary cell models, oocyte degeneration that
3 are associated with female reproductive
4 organs. So, no, not in humans, but we've
5 seen in vitro and in vivo animal studies.

6 BY MR. ZELLERS:

7 Q. Take a look, if you will, at
8 your report, Table 7, Page 21. The first
9 ingredient you list is d-Limonene?

10 A. Limonene, I believe, is how it's
11 pronounced.

12 Q. Limonene?

13 A. Yeah.

14 Q. That's a chemical found in the
15 peels of citrus fruit. Is that right?

16 A. I don't know if it comes from
17 the peels. I read that a while back. I'll
18 take your word for it. I know it's in
19 lemons. I believe it's in oranges, too, and
20 other citrus fruits.

21 And I know that there's a
22 cleanser that's got it in there.

23 Q. I misstated. For our record,
24 it's Page 22 where Table 7 begins.

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1 And I'd like to add one quick
2 point. You mentioned the rosin earlier,
3 Methyl Hydrogenated Rosinate. That's glue.
4 It's a film former. It adheres the fragrance
5 chemicals to the talc particles. So where
6 the talc particles go, the fragrance
7 chemicals will go.

8 We have a result here in which
9 d-Limonene was found to be cytotoxic against
10 Chinese hamster ovary cells in which the
11 inhibitory concentration of 50 percent was 50
12 micrograms per mL. That is a very, very low
13 concentration.

14 So, if there was d-Limonene
15 attached to a talc particle with the rosin
16 and that particular talc particle entered the
17 vagina and landed next to an ovary, I think
18 that data strongly suggests that those two
19 materials are not compatible and there would
20 be problems. That study makes it clear and
21 equivocal that d-Limonene is not compatible
22 with Chinese hamster ovary cells. I wouldn't
23 put my daughter's ovary at risk with it.

1 A. Oh.
2 Q. Is that right?

3 A. Yeah.

4 Q. d-Limonene is used as both a
5 fragrance and a flavoring. Is that right?

6 A. I believe so.

7 Q. If d-Limonene were associated
8 with the development of ovarian cancer,
9 wouldn't you expect to see higher rates of
10 ovarian cancer among people who handle fruit?

11 MS. O'DELL: Object to the form.

12 MR. ZELLERS: What are you
13 objecting to? That was a good
14 question.

15 A. So again we get to route of
16 exposure. I mean, the presumption is that
17 handling fruit, you know, doesn't transfer
18 the d-Limonene through the skin into the
19 blood and ultimately reach the ovaries.

20 And, you know, this matter --
21 peritoneal application, that's awfully close to
22 the ovaries, and, you know, as I said, I've
23 been asked to assume that it does enter the
24 vaginal cavity.

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1 BY MR. ZELLERS:

2 Q. In order to do a proper
3 scientific analysis, you have to make an
4 assessment of concentration. Correct?

5 A. Uh-huh.

6 Q. Yes?

7 A. Yes.

8 MS. O'DELL: Object to form.

9 BY MR. ZELLERS:

10 Q. You have to make an assessment
11 of dose response. Correct?

12 MS. O'DELL: Object to the form.

13 A. It depends. Again, I keep
14 telling you genotoxic materials -- they are
15 not thresholded.

16 BY MR. ZELLERS:

17 Q. It is --

18 A. One molecule is enough to cause
19 an increased risk and carcinogenicity.

20 Q. Is d-Limonene a genotoxic

21 material?

22 A. I don't believe it's been

23 classified as that, but cytotoxicity against

24 Chinese hamster ovary cells indicates that it

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1 could be against ovaries, at least in this
2 animal model.
3 Q. And what --
4 A. And you don't do those kind of
5 studies against humans. They're unethical.
6 Right? So the safety of d-Limonene has not
7 been established in human vaginas.

8 Q. In order to do a scientific
9 study, d-Limonene -- you would need to also
10 do an exposure analysis. Correct?

11 MS. O'DELL: Object to the form.

12 A. Not necessarily.

13 BY MR. ZELLERS:

14 Q. You would not need to do an
15 exposure analysis in order to lead to a
16 scientifically valid conclusion of the effect
17 of d-Limonene on a human?

18 MS. O'DELL: Object to the form.

19 A. You could, but you don't have
20 to. What kind of -- I mean, I guess in the
21 model that you want to rely upon, it seems to
22 be an important fact to you. But the fact is
23 it hasn't been done in humans in the vagina.

24

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1 model you are familiar with to assess the
2 risk in humans that does not include any type
3 of exposure assessment or analysis?

4 MS. O'DELL: Object to the form.

5 BY MR. ZELLERS:

6 Q. I don't want to sit here and
7 have you --

8 A. You asked --

9 Q. -- internet research --

10 A. -- the question. I'm going to
11 get you the answer.

12 Q. Well, I'm not asking you to do
13 internet research. What I'm asking you to
14 do --

15 A. This isn't -- it's not internet
16 research.

17 Q. Well, you're doing something on
18 your computer.

19 A. I'm looking for the name of the
20 Klimisch rating --

21 Q. Well, I'm okay if you supplement
22 your answer later on in the deposition.

23 A. Okay. That's fine.

24 Q. I just want to --

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1 BY MR. ZELLERS:

2 Q. An exposure analysis is an
3 important part of a risk assessment.
4 Correct?

5 MS. O'DELL: Object to the form,
6 asked and answered.

7 A. You've asked the question. I've
8 answered it previously.

9 BY MR. ZELLERS:

10 Q. And I'm assuming and recalling
11 your answer was "yes." Is that right?

12 MS. O'DELL: That's not correct.
13 Misstates his testimony.

14 BY MR. ZELLERS:

15 Q. Is an exposure analysis an
16 important part of a risk assessment?

17 A. The risk assessment --

18 MS. O'DELL: Objection; form.

19 A. -- that you presented in one of
20 your earlier exhibits says it is, but that's
21 not the only risk assessment model that there
22 is.

23 BY MR. ZELLERS:

24 Q. Tell me what risk assessment

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1 MS. O'DELL: Well, and if you
2 want to explain what you were doing and
3 respond, you're welcome to do that.

4 A. Klimisch rating is an evaluation
5 approach. It's a systemic approach for
6 evaluation of data, and it's got reliability
7 categories, so -- and that is a risk
8 assessment model.

9 BY MR. ZELLERS:

10 Q. That involves no exposure
11 assessment. Is that right?

12 A. It does not involve an exposure
13 assessment.

14 Q. Do you know the concentration of
15 d-Limonene in either baby powder or Shower to
16 Shower?

17 A. No.

18 MS. O'DELL: Object to the form.

19 A. It was not provided to me.

20 BY MR. ZELLERS:

21 Q. Similarly, you don't know what
22 dose of d-Limonene a woman would be exposed
23 to if she utilized either Shower to Shower or
24 baby powder. Correct?

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1 MS. O'DELL: Object to the form.
 2 A. That's right. I wasn't provided
 3 with that information.

4 BY MR. ZELLERS:

5 Q. In your list, you give us
 6 benzaldehyde?

7 MS. O'DELL: Which list are you
 8 referring to?

9 MR. ZELLERS: Page 22, Table 7.

10 MS. O'DELL: Fair enough. I
 11 just didn't know --

12 MR. ZELLERS: That's okay.

13 A. Benzaldehyde. That's correct.

14 BY MR. ZELLERS:

15 Q. Benzaldehyde. Do you know what
 16 benzaldehyde is?

17 A. Yes.

18 Q. What is it?

19 A. It's aldehyde of benzene.

20 Q. Artificial almond oil. Correct?

21 A. Yeah.

22 Q. It's used as a fragrance in
 23 lotions. Is that right?

24 MS. O'DELL: Object to the form.

1 oppose your motion to strike, and I
 2 object to your preamble and to
 3 directing the witness to answer a
 4 certain way. Dr. Crowley is
 5 endeavoring to answer your questions.

6 BY MR. ZELLERS:

7 Q. If -- assuming that benzaldehyde
 8 is artificial almond oil and is used as a
 9 fragrance in lotions, if it were associated
 10 with ovarian cancer, you would expect to see
 11 higher rates of ovarian cancer among users of
 12 almond-scented lotion. Correct?

13 MS. O'DELL: Object to the form,
 14 incomplete hypothetical.

15 A. Not necessarily.

16 BY MR. ZELLERS:

17 Q. Are you aware that benzaldehyde
 18 is also used as the flavoring in artificial
 19 almond extract?

20 A. No.

21 Q. Assuming that's true, if
 22 benzaldehyde were associated with the
 23 development of ovarian cancer, wouldn't you
 24 expect to see higher rates of ovarian cancer

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1 A. I don't know where it's used or
 2 not used.

3 BY MR. ZELLERS:

4 Q. Assuming that it's used as a
 5 lotion, lotions are applied topically to the
 6 skin. Is that right?

7 MS. O'DELL: Object to the form.

8 A. Generally, yeah. And we keep
 9 going down this rabbit hole. Just because
 10 you can rub it on the skin or swallow it
 11 doesn't mean it's safe for your eyes or, in
 12 the case of females, vaginas.

13 BY MR. ZELLERS:

14 Q. At some point Ms. O'Dell is
 15 going to have a chance to ask you questions,
 16 and you can pontificate as much as you want.
 17 I need, right now, if you can, just to try to
 18 answer my questions. Okay?

19 MS. O'DELL: He answered your
 20 question.

21 MR. ZELLERS: He's not answering
 22 my question, and I move to strike as
 23 nonresponsive.

24 MS. O'DELL: Fair enough. I

1 among people who use artificial almond
 2 extract?

3 MS. O'DELL: Object to the form.

4 A. Again, artificial almond extract
 5 is generally eaten. We put it in cookies.
 6 We have a cooking -- by the way, I love
 7 almond flavor. You know, it's not being
 8 applied to the peroneal area, and it's
 9 also -- you know, it had to check its
 10 permeability and absorption through the skin.

11 Just, you know, sort of blanket
 12 statements that are broad like that don't put
 13 the analysis that I've done in the proper
 14 perspective.

15 BY MR. ZELLERS:

16 Q. Is there -- are you finished?

17 A. Yes.

18 Q. Is there any evidence that
 19 exposure to artificial almond extract
 20 contributes to the development of ovarian
 21 cancer?

22 MS. O'DELL: Object to the form.

23 A. You asked about ovarian cancer.

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1 BY MR. ZELLERS:

2 Q. Well --

3 A. Here is what the data that I did
4 find stated, was that there was a positive in
5 sister chromatid exchange, which is
6 genotoxicity, with human lymphocytes from
7 healthy non-smoking donors. It was also
8 found to induce formulation of stable
9 DNA-protein cross-links in cultured human
10 lymphoma cells. That's from TOXNET.

11 Demir -- I don't know how to
12 pronounce it -- Kocaoglu and Kaya reported
13 that it may have significant genotoxic
14 effects.

15 It was cytogenic at 50 nanomoles
16 per liter in 24 hours against Chinese hamster
17 ovary cells. Nanomoles per liter. That's a
18 very low concentration.

19 Sister chromatid exchange in
20 Chinese hamster ovary cells published by
21 Galloway.

22 So again, that's -- that's a
23 direct -- direct evidence of benzaldehyde
24 interacting with a cell, and that's different

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1 Q. You have not done an analysis
2 with respect to routes of exposure with
3 regard to benzaldehyde. Correct?

4 MS. O'DELL: Object to the form.

5 A. I did. I did look at all the
6 available information on pharmacokinetics;
7 absorption, distribution, metabolism, and
8 elimination. And --

9 BY MR. ZELLERS:

10 Q. Where is that in your report?

11 A. It would be in the appendices.

12 Q. All right.

13 A. So the PubChem link, it lists
14 all of that.

15 Q. Do you know --

16 A. The pharmacologies -- I'm sorry.
17 I wasn't done.

18 Q. All right. Please finish your
19 answer.

20 A. Yeah. The pharmacology for each
21 and every one of those chemicals I looked at
22 in depth.

23 Q. Do you know the concentration of
24 benzaldehyde in baby powder or Shower to

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1 than cells on your tongue, and that's
2 different than cells on your skin.

3 BY MR. ZELLERS:

4 Q. It is not a --

5 A. So --

6 Q. I'm sorry. Finish your answer.

7 A. So that's what I'm reporting.

8 And companies that are going to develop
9 products that are intended for topical
10 administration take those kinds of things
11 into consideration. That's why they do eye
12 irritation and eye sens- -- you know, skin
13 sensitization studies.

14 If a product is going to be
15 applied to the perineal area, companies are
16 going to consider, well, that may enter the
17 anus. It could enter the vagina. What is a
18 potential outcome?

19 Those are standard and typical
20 considerations when companies develop
21 products.

22 Q. Routes of exposure are
23 important. Correct?

24 A. Yes.

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1 Shower?

2 A. I think you've asked me this
3 question now at least a half dozen times. I
4 have not been provided with the compositions.

5 Q. The same thing for what dose of
6 this chemical a woman would be exposed to if
7 she used baby powder or Shower to Shower.

8 Correct?

9 MS. O'DELL: Object to the form

10 of that question and the question
11 before.

12 A. Again, that information was
13 requested and was not provided.

14 BY MR. ZELLERS:

15 Q. Looking at Table 7, Pages 21 to
16 26, can you point to any chemical where there
17 is evidence that the chemical contributes to
18 ovarian cancer in humans?

19 MS. O'DELL: Object to the form.

20 A. Give me a minute.

21 para-Cresol. Women exposed in their
22 workplace to varnishes that contained mixed
23 Cresols had increased gynecological problems
24 such as menstrual disorders and hormonal

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<p>1 disturbances. An increased frequency of 2 perinatal mortality and abnormal development 3 of newborn infants was also reported. 4 BY MR. ZELLERS: 5 Q. Do any of those studies relate 6 to or reference an increased risk of ovarian 7 cancer? 8 MS. O'DELL: Object to the form. 9 A. Ovarian cancer in humans or in 10 animals? I feel like -- 11 BY MR. ZELLERS: 12 Q. In humans, yes. 13 A. -- we keep going back and forth 14 here. 15 Q. Let's limit it to humans. 16 A. Pardon me? 17 Q. In humans. 18 MS. O'DELL: Object to the form. 19 A. No, they have not been studied 20 for ovarian cancer in humans. 21 BY MR. ZELLERS: 22 Q. I want to ask you the same 23 question with respect to Shower to Shower. 24 So Table 16, can you point to any chemical</p>	<p>Page 234</p> <p>1 your answer? 2 A. Yeah. 3 Q. In your report, you claim that 4 four chemicals in baby powder have been 5 identified by IARC, the International Agency 6 for Research on Cancer, as potential 7 carcinogens. Is that right? And I'm looking 8 at Page 12. 9 A. Yes. 10 Q. You list styrene, d-Limonene, 11 coumarin -- 12 A. Yes. 13 Q. -- and eugenol? 14 A. Yes. 15 Q. You also claim, on Page 12, that 16 three chemicals in Shower to Shower have been 17 identified by IARC as possible carcinogens. 18 Is that right? 19 A. Yes. 20 Q. Benzophenone, coumarin, and 21 eugenol. Is that right? Those are the three 22 that you identified for Shower to Shower? 23 A. Benzophenone, coumarin, and 24 eugenol. I also identified musk ketone.</p>
<p>1 where there is evidence that the chemical 2 contributes to ovarian cancer in humans? 3 A. A human study? You want to -- 4 Q. Yes. 5 A. You're choosing to ignore all 6 the animal studies and in vitro studies? 7 Just -- 8 Q. I'm not asking -- 9 A. Just so we're clear on that. 10 Q. I'm not looking to argue with 11 you. Okay? I've asked you a question. I'd 12 like you to try to answer to the best of your 13 ability? 14 MS. O'DELL: I will object. I'm 15 going to object to the form of the 16 question and just ask if you would let 17 Dr. Crowley finish. 18 A. Yeah. So you're asking for 19 human studies only. 20 BY MR. ZELLERS: 21 Q. Yes. 22 A. Right? There isn't one because 23 these haven't been studied in human vaginas. 24 Q. In your -- are you finished with</p>	<p>Page 235</p> <p>1 That's the Scientific Committee on Health and 2 Environmental Risks in Europe. You also 3 didn't mention para-Cresol, which the EPA 4 considers to be possibly carcinogenic. 5 Q. I'm going to get to musk ketone 6 and para-Caresol -- or Cresol, but right now 7 I want to just limit my questions to the IARC 8 references that you make. 9 A. Okay. 10 Q. Understood? 11 A. Sure. 12 Q. You're familiar with the -- 13 well, and so our record is clear, you 14 identified four chemicals or fragrance 15 chemicals with baby powder that are 16 potentially -- that are potential carcinogens 17 according to IARC. Is that right? Styrene, 18 d-Limonene, coumarin, and eugenol. 19 A. Isn't that the same question you 20 just asked me? 21 Q. Yes, but you then added in musk 22 ketone and para-Cresol. Those two you cite 23 other sources for them being identified as a 24 possible or potential carcinogen. Is that</p>

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1 right? 2 A. Yes. 3 MS. O'DELL: Object to the form. 4 BY MR. ZELLERS: 5 Q. I just want, right now, to talk 6 about the IARC references that you make. 7 You're familiar with the classification 8 system that IARC has established. Is that 9 right? 10 A. Yes. 11 Q. Group 4 chemicals are probably 12 not carcinogenic to humans. Is that right? 13 A. Is that a question? 14 Q. Yes. 15 A. Yeah, Group 4 is probably not 16 carcinogenic to humans. 17 Q. Group 3 chemicals are not 18 classifiable as to the carcinogenicity to 19 humans. Right? 20 A. Yes. 21 Q. That category is used where the 22 evidence of carcinogenicity is inadequate in 23 humans and inadequate or limited in 24 experimental animals. Correct?	Page 238	1 on my computer. 2 Q. If you look at Deposition 3 Exhibit 25, the classification system in the 4 preamble, for Group 3, the chemical is not 5 classifiable as to its carcinogenicity to 6 humans. That's the title of that group. Is 7 that right? 8 A. That's what it says, "The agent 9 is not classifiable as to its carcinogenicity 10 to humans." 11 Q. The description -- at least the 12 first paragraph of the description for 13 Group 3, "This category is used most commonly 14 for agents for which the evidence of 15 carcinogenicity is inadequate in humans and 16 inadequate or limited in experimental 17 animals." 18 Did I read this correctly? 19 MS. O'DELL: Object to the form. 20 A. Yeah, I believe you read that 21 faithfully. 22 BY MR. ZELLERS: 23 Q. All right. Group 2B -- 24 A. Well, wait a minute. You need	Page 240
1 A. No. That's only half of it. 2 The other part of that is evidence of 3 carcinogenicity is inadequate in humans but 4 sufficient in experimental animals, but 5 strong evidence that the mechanism of 6 carcinogenicity in experimental animals may 7 not operate in humans, or agents that don't 8 fall into any other group. 9 (Exhibit No. 25 marked) 10 BY MR. ZELLERS: 11 Q. So we have a clear record, 12 Deposition Exhibit 25 is the preamble to the 13 IARC monographs on the human evaluation of 14 carcinogenic risks to humans. Is that right? 15 A. That's what it says. 16 MS. O'DELL: You said 25? 17 MR. ZELLERS: 25. 18 MS. O'DELL: Thank you. 19 BY MR. ZELLERS: 20 Q. Are you familiar with this -- 21 A. I have seen -- 22 Q. -- preamble? 23 A. I have seen this. I also have 24 the IARC classifications from their website	Page 239	1 to read the next paragraph, because that's 2 important, in Group 3. "Exceptionally, 3 agents for which the evidence of 4 carcinogenicity is inadequate in humans but 5 sufficient in experimental animals may be 6 placed in this category when there is strong 7 evidence that the mechanism of 8 carcinogenicity in experimental animals does 9 not operate in humans." 10 Q. Are you done? 11 A. So -- yeah. 12 Q. Okay. 13 A. So -- 14 Q. I don't want to have a 15 discussion -- I mean, I just asked for the 16 definition. 17 A. Well, your only picking half of 18 it is part of the problem. 19 Q. Is there anything else you want 20 to read into the record for the definition of 21 a Group 3 IARC chemical? 22 A. Yep. 23 Q. Read what you want to read, and 24 let's move on.	Page 241

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1 A. The third part of that is agents
2 that don't fall into any other group. Those
3 are the three criteria.
4 Q. Group 2B under the IARC
5 classification is the agent is possibly
6 carcinogenic to humans. Is that right?
7 A. There's three parts to Group 2B.
8 Limited evidence of carcinogenicity in humans
9 and less than sufficient evidence of
10 carcinogenicity in experimental animals or --
11 operative word "or" -- inadequate evidence of
12 carcinogenicity in humans but sufficient
13 evidence of carcinogenicity in experimental
14 animals.
15 And Part 3 is also an "or."
16 Inadequate evidence of carcinogenicity in
17 humans and less than sufficient evidence of
18 carcinogenicity in experimental --
19 THE REPORTER: I'm sorry. Read
20 that -- read that slower again, the
21 last --
22 THE WITNESS: I'm sorry. I'll
23 start it --
24 THE REPORTER: "In humans."

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1 potential carcinogen is -- strike that.
2 The first fragrance chemical
3 that you claim IARC has classified as a
4 potential carcinogen is styrene. Is that
5 right?
6 A. Yeah.
7 Q. Potential carcinogen is not a
8 category recognized by IARC. Is that right?
9 A. No. No. They have the
10 categories that we --
11 Q. What we just talked about?
12 A. Yeah.
13 Q. Styrene has been classified by
14 IARC as a 2B chemical. Is that right?
15 A. I believe that's correct. Yeah,
16 2B.
17 Q. As we discussed, this category
18 is used when there is limited evidence of
19 carcinogenicity in humans and less than
20 sufficient evidence of carcinogenicity in
21 experimental animals. Is that right?
22 MS. O'DELL: Object to the form.
23 A. Again, only partially correct.
24 It can also be a circumstance where there's

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1 A. Inadequate evidence of
2 carcinogenicity in humans and less than
3 sufficient evidence of carcinogenicity in
4 experimental animals but with supporting
5 evidence from mechanistic and other relevant
6 data.
7 BY MR. ZELLERS:
8 Q. Group 2B, the classification by
9 IARC, is the agent is possibly carcinogenic
10 to humans. Is that right?
11 A. Yes.
12 Q. Group 2A chemicals are probably
13 carcinogenic to humans. Is that right?
14 A. Yes.
15 Q. Group 1 chemicals are
16 carcinogenic to humans. Is that right?
17 A. Yes.
18 Q. To be clear, none of the
19 fragrance chemicals in baby powder or Shower
20 to Shower have been classified as a Group 1
21 agent by IARC. Is that right?
22 A. That's correct.
23 Q. The first fragrance chemical
24 that you claim IARC has classified as

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1 inadequate evidence of carcinogenicity in
2 humans but sufficient evidence of
3 carcinogenicity in animals.
4 BY MR. ZELLERS:
5 Q. Would you agree IARC has not
6 concluded that styrene is carcinogenic in
7 humans? Correct?
8 A. Okay. They've concluded it's in
9 Group 2B, which is possible carcinogenic to
10 humans.
11 And I need to request a break
12 because I need to blow my nose.
13 MR. ZELLERS: Let's take a
14 break.
15 THE WITNESS: Is that all right?
16 MR. ZELLERS: That's a very
17 legitimate reason.
18 THE VIDEOGRAPHER: Going off the
19 record, the time is 2:53 p.m.
20 (Recess from 2:53 p.m. to
21 3:05 p.m.)
22 THE VIDEOGRAPHER: Back on the
23 record, the time is 3:05 p.m.
24 (Exhibit No. 26 marked)

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<p>1 BY MR. ZELLERS:</p> <p>2 Q. Dr. Crowley, Deposition</p> <p>3 Exhibit 26 is the IARC monograph with respect</p> <p>4 to styrene. Is that correct?</p> <p>5 A. I think I found more than one of</p> <p>6 them. Which one is this? This is Volume 82?</p> <p>7 Q. Is Exhibit 26 a -- an IARC</p> <p>8 document?</p> <p>9 MS. O'DELL: Object to the form.</p> <p>10 A. I'm going to take your word for</p> <p>11 it, but I can't say with certainty because I</p> <p>12 don't see IARC -- oh, there it is on the</p> <p>13 second page. It says "IARC monograph</p> <p>14 Volume 82." So, yeah, it sure looks like it.</p> <p>15 BY MR. ZELLERS:</p> <p>16 Q. As we discussed before, an</p> <p>17 ingredient can cause or contribute to the</p> <p>18 development of one type of cancer but not</p> <p>19 another type of cancer. Correct?</p> <p>20 A. Yeah, that's -- that's true.</p> <p>21 Q. Isn't it true that in human</p> <p>22 studies, styrene exposure has only been</p> <p>23 associated with an increased risk in</p> <p>24 lymphatic and hematopoietic neoplasms? And</p>	<p>Page 246</p> <p>1 MS. O'DELL: So you do not know</p> <p>2 the year of this publication?</p> <p>3 MR. ZELLERS: I do not know the</p> <p>4 year of this other than I believe it to</p> <p>5 be the most recent IARC monograph with</p> <p>6 respect to styrene. All I can tell you</p> <p>7 is it's after 1994, and it is part of</p> <p>8 the IARC monographs in Volume 82.</p> <p>9 A. So I'm looking at the copy I</p> <p>10 found, and it --</p> <p>11 BY MR. ZELLERS:</p> <p>12 Q. Oh, I'm sorry. So I can</p> <p>13 identify Deposition Exhibit 26 as a 2002 IARC</p> <p>14 monograph.</p> <p>15 A. Okay. So this is only part of</p> <p>16 it, because I also considered this particular</p> <p>17 document. It looks to me like you've</p> <p>18 provided me with copies up through 520 --</p> <p>19 Page 522. The actual report I found was 114</p> <p>20 pages long, and it contains -- it goes up to</p> <p>21 Page 550.</p> <p>22 Q. I have just given you, in</p> <p>23 Exhibit 26, excerpts from the monograph. The</p> <p>24 first page of the exhibit was 437. The last</p>
<p>Page 247</p> <p>1 I'm looking at the IARC monograph,</p> <p>2 Exhibit 26, at Page 520.</p> <p>3 MS. O'DELL: Object to the form.</p> <p>4 A. Can you direct me to --</p> <p>5 BY MR. ZELLERS:</p> <p>6 Q. Sure.</p> <p>7 A. -- where on Page 520? I'm going</p> <p>8 to trust that you're faithful in reading it</p> <p>9 to me.</p> <p>10 The one thing I'd like to verify</p> <p>11 is there are multiple IARC examinations of</p> <p>12 styrene, so do you know which -- this is from</p> <p>13 Volume 82, but which year is that? Do you</p> <p>14 know?</p> <p>15 Q. Well, looking at the cover page</p> <p>16 of Exhibit 26, the IARC monograph states,</p> <p>17 "This substance was considered by previous</p> <p>18 working groups in 1978, 1987, and 1994.</p> <p>19 Since that time, new data have become</p> <p>20 available, and these have been incorporated</p> <p>21 into the monograph and taken into</p> <p>22 consideration in the present evaluation."</p> <p>23 That's what I know with respect</p> <p>24 to the year.</p>	<p>Page 249</p> <p>1 page I provided you was 522, so I will</p> <p>2 acknowledge these are just excerpts --</p> <p>3 A. Okay.</p> <p>4 Q. -- from the monograph.</p> <p>5 MS. O'DELL: Well, fair enough.</p> <p>6 Thank you for acknowledging that. And</p> <p>7 I'll just note for the record, so it's</p> <p>8 clear, Exhibit 26 skips from Page 438</p> <p>9 to 517, and then it's 517 to 522, and</p> <p>10 the remainder is omitted.</p> <p>11 BY MR. ZELLERS:</p> <p>12 Q. Doctor, I'm ready to continue.</p> <p>13 Are you ready?</p> <p>14 A. All right.</p> <p>15 Q. I'm pointing you to, in</p> <p>16 Exhibit 26, the section on human</p> <p>17 carcinogenicity data, Section 5.2 that begins</p> <p>18 on Page 518. Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. Are you aware of any human</p> <p>21 studies associating styrene exposure with an</p> <p>22 increased risk of -- well, let me withdraw</p> <p>23 that question.</p> <p>24 In this section, IARC references</p>

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1 a human study relating to an increased risk 2 of lymphatic and hematopoietic neoplasm with 3 styrene exposure. Is that generally 4 accurate? 5 MS. O'DELL: Object to the form. 6 A. I mean, they -- they talk about 7 a number of studies. If you go to Page 519, 8 the second to last paragraph, "There have 9 also been reports of increased risks of 10 rectal, pancreatic, and nervous system 11 cancers in some of the cohort and 12 case-control studies. The numbers of cases 13 were quite small in these studies, and most 14 of the larger cohort studies have not yielded 15 similar findings. Many of the cohort studies 16 did not examine these sites in detail." 17 So I don't think it's just 18 limited to those. 19 BY MR. ZELLERS: 20 Q. Let me cut to the chase and ask 21 you my question -- 22 A. Okay. 23 Q. -- and then we can hopefully 24 move along.	Page 250 1 It's very fair for -- you've asked him 2 does the monograph refer to ovarian 3 cancer, and it's very fair for him to 4 be able to examine that document and 5 answer your question and not rely on 6 this truncated, incomplete exhibit. 7 MR. ZELLERS: The exhibit I 8 provided to him was the summary of data 9 reported in evaluation for human 10 carcinogenicity data. 11 BY MR. ZELLERS: 12 Q. But my question to you, 13 Dr. Crowley, is: Are you aware of any study 14 that associates styrene exposure with an 15 increased risk of ovarian cancer in humans? 16 MS. O'DELL: Object to the form. 17 A. No. 18 BY MR. ZELLERS: 19 Q. If I ask you the same questions 20 as I asked before, you don't know the dose or 21 the amount or the concentration of styrene in 22 the baby powder or Shower to Shower product. 23 Correct? 24 MS. O'DELL: Object to the form.
Page 251 1 There are no human studies that 2 associate styrene exposure with an increased 3 risk of ovarian cancer in humans. Is that 4 right? 5 MS. O'DELL: Object to the form. 6 A. I'm going to take my new copy, 7 and I'm going to do a search. 8 BY MR. ZELLERS: 9 Q. Again, I'm objecting to you 10 doing internet research to try to answer my 11 questions. 12 MS. O'DELL: Excuse me. He's 13 not doing internet research. As he's 14 noted to you, that he was provided, in 15 Exhibit 26, an incomplete monograph, 16 and he has the full monograph before 17 him. And so it's very fair to answer 18 your question -- 19 MR. ZELLERS: Ms. O'Dell. 20 MS. O'DELL: No, no, no. Let me 21 finish. 22 MR. ZELLERS: If he is 23 referring -- 24 MS. O'DELL: No. Let me finish.	Page 253 1 A. Johnson & Johnson did not 2 provide that information to enable that kind 3 of assessment. 4 BY MR. ZELLERS: 5 Q. The same -- 6 A. It was requested. 7 Q. The same statement: You do not 8 know the amount of exposure or the duration 9 of exposure of any individual in this case. 10 Correct? 11 MS. O'DELL: Object to the form. 12 A. The same answer: Information 13 was requested, and Johnson & Johnson did not 14 provide that to enable that kind of analysis. 15 BY MR. ZELLERS: 16 Q. Do you agree that the studies -- 17 the human studies with respect to styrene are 18 characterized by IARC as generally small, 19 statistically unstable, and often based on 20 subgroup analyses? 21 MS. O'DELL: Object to the form. 22 A. Could you please point me to 23 where you read that? 24

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<p>1 BY MR. ZELLERS:</p> <p>2 Q. Sure. Take a look --</p> <p>3 A. Which page?</p> <p>4 Q. Yes. Page 520. So at the very</p> <p>5 top of 520 -- this, again, is in the section</p> <p>6 on human carcinogenicity data -- IARC states,</p> <p>7 "The increased risks for lymphatic and</p> <p>8 hematopoietic neoplasms observed in some of</p> <p>9 the studies are generally small,</p> <p>10 statistically unstable, and often based on</p> <p>11 subgroup analyses. These findings are not</p> <p>12 very robust."</p> <p>13 Did I read that correctly?</p> <p>14 A. I believe so.</p> <p>15 Q. All right.</p> <p>16 A. I think one other thing we</p> <p>17 should talk about with respect to styrene is</p> <p>18 its metabolite.</p> <p>19 MR. ZELLERS: Doctor, I'm going</p> <p>20 to object because I just need you to</p> <p>21 answer my questions.</p> <p>22 BY MR. ZELLERS:</p> <p>23 Q. And my question was: Did I read</p> <p>24 that correctly?</p>	<p>Page 254</p> <p>1 try to answer my questions as best you can.</p> <p>2 Is it true that in animal</p> <p>3 studies styrene exposure has only been</p> <p>4 associated with an increased incidence of</p> <p>5 pulmonary adenomas and carcinomas in mice?</p> <p>6 MS. O'DELL: Object to the form.</p> <p>7 A. Can you please --</p> <p>8 BY MR. ZELLERS:</p> <p>9 Q. Sure.</p> <p>10 A. -- direct me to where you're --</p> <p>11 Q. Take a look at the IARC</p> <p>12 monograph. I'm now looking at the Section</p> <p>13 5.3, Exhibit 26, Page 520, animal</p> <p>14 carcinogenicity data.</p> <p>15 Do you see that?</p> <p>16 A. Yes. So styrene was tested for</p> <p>17 carcinogenicity in mice in an inhalation</p> <p>18 study and four oral gavage studies. That's</p> <p>19 what you're talking about. Right?</p> <p>20 Q. Yes.</p> <p>21 A. All right.</p> <p>22 Q. It was only associated with an</p> <p>23 increased incidence of pulmonary adenomas and</p> <p>24 carcinomas in mice. Is that right?</p>
<p>1 A. The answer --</p> <p>2 MS. O'DELL: Object to the form.</p> <p>3 A. Yeah. You did read it</p> <p>4 correctly, but as long as we're talking about</p> <p>5 the safety of styrene in human studies, we</p> <p>6 can't ignore its metabolite.</p> <p>7 Styrene-7,8-oxide has been</p> <p>8 implicated and found to be carcinogenic and</p> <p>9 genotoxic in virtually every study that has</p> <p>10 ever been done with it. Metabolism of</p> <p>11 styrene to those metabolites have also been</p> <p>12 demonstrated both in humans and in animals to</p> <p>13 be carcinogenic.</p> <p>14 So while you're picking and</p> <p>15 choosing certain portions of the IARC</p> <p>16 monograph, let's consider the thing in total,</p> <p>17 all of the evidence.</p> <p>18 MR. ZELLERS: Move to strike as</p> <p>19 nonresponsive.</p> <p>20 BY MR. ZELLERS:</p> <p>21 Q. I have not -- my question was:</p> <p>22 Did I read that statement correctly from</p> <p>23 IARC? This is not your opportunity to just</p> <p>24 pontificate. I'll move on, but I need you to</p>	<p>Page 255</p> <p>1 A. That's what it says. But let's</p> <p>2 also jump down two paragraphs. "Styrene-7,8-</p> <p>3 oxide is a major metabolite of styrene and</p> <p>4 has been previously evaluated by IARC. The</p> <p>5 evaluation at that time was that there was</p> <p>6 sufficient evidence in experimental animals</p> <p>7 for the carcinogenicity of styrene-7,8-</p> <p>8 oxide."</p> <p>9 Q. What is styrene-7,8-oxide?</p> <p>10 A. It's the metabolite. So when</p> <p>11 styrene is absorbed, it's metabolized to the</p> <p>12 7,8-oxide.</p> <p>13 So this is very similar to</p> <p>14 certain drugs. There are drugs called</p> <p>15 prodrugs. The chemical that you swallow has</p> <p>16 zero biological activity. However, once it's</p> <p>17 been metabolized, the metabolite is</p> <p>18 pharmacologically active. That's the case</p> <p>19 here with styrene.</p> <p>20 Q. This is an animal study.</p> <p>21 Correct?</p> <p>22 A. It's an animal study.</p> <p>23 Q. All right. d-Limonene. You</p> <p>24 claim that IARC has identified d-Limonene as</p>

<p>1 a potential carcinogen. Is that right? And 2 I'm looking at your report. I believe it was 3 Page 12. 4 A. Yes. 5 Q. d-limonene -- strike that. 6 (Exhibit No. 27 marked) 7 BY MR. ZELLERS: 8 Q. Exhibit 27 is again excerpts 9 from the IARC monograph on d-Limonene? 10 A. I'm going to pull up the entire 11 monograph. 12 MS. O'DELL: So just for the 13 record, Exhibit 27 starts at Page 307 14 and goes to 308, then skips to 320 15 and -- 16 MR. ZELLERS: It's just as with 17 the styrene monograph. What I have 18 done here is to photocopy the sections 19 relating to human carcinogenicity data 20 and animal carcinogenicity data. 21 MS. O'DELL: And feel free to 22 look at the whole monograph if you need 23 to, Dr. Crowley. 24 THE WITNESS: I have it.</p>	<p>Page 258</p> <p>1 carcinogenicity is inadequate in humans and 2 inadequate or limited in animals, or the 3 evidence of carcinogenicity in humans is 4 inadequate but sufficient in experimental 5 animals with strong evidence that the 6 mechanism doesn't relate. That's what the 7 classification -- which we've read into the 8 record previously. 9 Q. The summary of Group 3 10 classification by IARC is that the agent is 11 not classifiable as to its carcinogenicity to 12 humans. Is that right? 13 MS. O'DELL: Object to form. 14 BY MR. ZELLERS: 15 Q. That is -- I'm reading from 16 Exhibit 25. 17 A. Yeah. There's three elements 18 that go into the group classifications, and 19 you're only reading the first one. You're 20 not reading all three. 21 Q. Now, Doctor, in fairness -- 22 MS. O'DELL: Let him finish, 23 sir. 24 A. Excuse me. I wasn't finished.</p>
<p>1 BY MR. ZELLERS: 2 Q. Dr. Crowley, IARC has classified 3 d-Limonene as a Group 3 agent. Is that 4 right? 5 A. I believe that's correct. 6 Q. The first sentence, as we read 7 before, of the definition of a Group 3 8 classification means that the chemical is not 9 classifiable as to its carcinogenicity in 10 humans. Is that right? 11 MS. O'DELL: Object to the form. 12 BY MR. ZELLERS: 13 Q. That's what the Group 3 14 classification means? 15 A. That's correct, not 16 classifiable. 17 Q. Do you agree that IARC has not 18 identified d-Limonene as a potential 19 carcinogen, but really what IARC has done is 20 determined there is no adequate evidence to 21 say that it is a carcinogen? 22 A. I would state that IARC has 23 classified it as Group 3, which means there's 24 evidence of -- the evidence of</p>	<p>Page 259</p> <p>1 BY MR. ZELLERS: 2 Q. You have to answer my question. 3 I'm reading the title. Is that right? 4 I'm not reading the definitions. 5 I'm reading the title. Did I read the title 6 correctly? 7 A. I think so. 8 Q. All right. And I don't mean to 9 unnecessarily cut you off, but we have had an 10 extensive discussion, both of us, in terms of 11 the definitions. Correct? 12 A. Right. 13 Q. All right. 14 A. And we have. And I think that 15 it's pretty clear that IARC considers both 16 human and animal studies when they come up 17 with these classifications. 18 Q. Isn't it true that there are no 19 human studies linking the use of d-Limonene 20 to any type of cancer? 21 A. The IARC monograph states that 22 there was no data available to the working 23 group on studies of cancer in humans with 24 d-Limonene. That's correct.</p>

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1 Q. Isn't it also true that in
2 animal studies the only potential association
3 between d-Limonene was found in renal tubular
4 tumors?

5 A. Renal tubular adenomas and
6 carcinomas, but I believe that there was a
7 co-carcinogen effect demonstrated, if my
8 memory is correct, in a lung model.

9 Q. In an animal study. Correct?

10 A. Yeah, that was an animal study.

11 Q. Let me ask you a couple --

12 A. So --

13 Q. Are you done?

14 A. I was just going to say, you
15 know, what that means is that if it's present
16 with a known carcinogen, it promotes
17 carcinogenesis.

18 Q. In animals. Correct? Or in
19 the -- in the particular animal study --

20 A. Yeah, in that particular study.

21 MS. O'DELL: Object to the form.

22 BY MR. ZELLERS:

23 Q. Coumarin. You state in your
24 report that coumarin is both a potential

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1 BY MR. ZELLERS:

2 Q. Well, I'll ask you a couple
3 specifically.

4 MS. O'DELL: You know, that's a
5 little unfair.

6 A. Do you trust me enough to
7 anticipate?

8 BY MR. ZELLERS:

9 Q. No, I don't.

10 MS. O'DELL: I would say, from
11 my standpoint, listen to his questions,
12 answer the questions, and we'll be
13 better off.

14 BY MR. ZELLERS:

15 Q. It's true, correct, that there
16 are no human studies linking use of coumarin
17 to any type of cancer?

18 MS. O'DELL: Object to the form.

19 A. I don't know that I would phrase
20 it that way. The IARC monograph says that no
21 data were available to the working group on
22 studies of cancer in humans for -- for
23 coumarin.

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1 carcinogen and a possible carcinogen. Is
2 that right?

3 A. I believe so.

4 Q. In fact, though, according to
5 IARC, coumarin is also a Group 3 agent. Is
6 that right?

7 A. That's correct, it's Group 3.

8 (Exhibit No. 28 marked)

9 BY MR. ZELLERS:

10 Q. Deposition Exhibit 28 is the
11 IARC coumarin monograph excerpts. If I asked
12 you all the same set of questions --

13 A. I'm probably going to give you
14 the same answers.

15 Q. -- with respect to coumarin that
16 I asked you with d-Limonene, we'd get the
17 same answers. Correct?

18 MS. O'DELL: Object --

19 A. Yes.

20 MS. O'DELL: Object to the form.

21 BY MR. ZELLERS:

22 Q. I'll ask you a couple --

23 MS. O'DELL: Maybe. Maybe not.

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1 BY MR. ZELLERS:

2 Q. Isn't it also true that in
3 animal studies, the only potential
4 association that has been found is lung -- or
5 strike that -- are lung tumors,
6 hepatocellular tumors, and renal tubal
7 adenomas?

8 A. Alveolar/bronchiolar tumors,
9 adenomas, and carcinomas in both males and
10 females, hepatocellular adenomas in females,
11 and marginal incidence in squamous cell
12 papillomas and carcinomas of the stomach.

13 Q. Those are all animal studies.

14 Correct?

15 A. Correct. I'm going to look at
16 this second one.

17 Hepatocellular tumors, and --
18 that's in mice. Now, I spent my New Year's
19 down at the coast, and I did -- at the beach,
20 and I did thumb through these, and I feel
21 like there was another one that demonstrates
22 that here, and I want to go look at it.

23 In rats, non-neoplastic
24 cholangiolitis, non-bile duct carcinomas.

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<p>1 Q. What type of animal study was 2 that? 3 A. That was a rat. 4 Q. With any of these animal 5 studies, do you know the dose of the chemical 6 that the animals were exposed to? 7 A. Yeah. They're present here in 8 the -- in the report. 9 Q. Eugenol. Eugenol is -- strike 10 that. 11 You state in your report that 12 eugenol is both a potential carcinogen and a 13 possible carcinogen. Is that right? 14 Page 12. 15 A. I'm actually on Page 21. I'm 16 sorry. 17 Coumarin and eugenol are not 18 classifiable. I think that's the word I 19 used. 20 Q. In fact, as with d-Limonene and 21 coumarin, eugenol is classified by IARC as a 22 Group 3 agent. Is that right? 23 A. Yes. 24 Q. At the risk of drawing another</p>	<p>Page 266</p> <p>1 IARC's assessment and classification, you'd 2 give me the same answers. Correct? 3 MS. O'DELL: Object to the form. 4 A. Yeah, so, I mean, the entire 5 IARC monograph is lengthy. In the case of 6 coumarin, they -- they actually have 7 Section 4, other data relevant to an 8 evaluation of carcinogenicity and its 9 mechanism. And so there they looked at the 10 pharmacokinetics; absorption, distribution, 11 metabolism, and excretion. That's on 12 Page 202 of the coumarin monograph, which I 13 don't think you had in your cut. 14 So, you know, there's a lot of 15 factors that go into these carcinogenicity 16 examinations by IARC or even NTP. 17 BY MR. ZELLERS: 18 Q. IARC is made up of a number of 19 experts who come together to look at the 20 carcinogenicity of certain chemicals. Is 21 that right? And ingredients? 22 A. It's an expert group, yeah. 23 Q. Yeah. And at least with respect 24 to IARC and the experts that are a part of</p>
<p>1 objection from counsel for the plaintiffs, if 2 I ask you the same questions regarding 3 eugenol that I have asked relating to 4 coumarin and d-Limonene, as relates to the 5 meaning of a Group 3 classification by IARC, 6 you'd give me the same answers. Right? 7 MS. O'DELL: Object to the form. 8 And because I don't believe that's a 9 fair way to ask those questions. If 10 you've got the questions, ask him, but, 11 you know -- 12 BY MR. ZELLERS: 13 Q. You can answer. 14 MS. O'DELL: It's a different -- 15 it's a different monograph. It's a 16 different circumstance, and he should 17 be able to have the opportunity to 18 clarify. 19 BY MR. ZELLERS: 20 Q. And he does have every 21 opportunity. But assuming I'm asking you all 22 the same set of questions with respect to 23 eugenol as I asked you with d-Limonene and 24 with coumarin, at least as it relates to</p>	<p>Page 267</p> <p>1 IARC's analysis for d-Limonene, coumarin, and 2 eugenol, they have determined that those are 3 all Group 3 chemicals, and the definition -- 4 or at least the statement of a Group 3 is 5 that the agent is not classifiable as to its 6 carcinogenicity to humans. Correct? 7 MS. O'DELL: Object to the form. 8 A. Yeah, that's right. And you've 9 also got to consider what routes of 10 administration they examined. Right? 11 So, you know, if you look at the 12 coumarin monograph, you don't find where it's 13 been administered vaginally in any animal to 14 ascertain whether that would pose a risk. 15 (Exhibit No. 29 marked) 16 BY MR. ZELLERS: 17 Q. Exhibit 29 are the excerpts from 18 the IARC eugenol monograph. 19 A. Is this Monograph 36? Yeah, 20 Volume 36. 21 So, again, the entire monograph 22 that I have is 363 pages long. 23 Q. You have that, and you have that 24 in front of you. Is that right?</p>

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1 A. I have my PDF open on my
2 computer.

3 Q. All right. It's true, is it
4 not, that there are no human studies linking
5 use of eugenol to any type of cancer? Is
6 that right?

7 MS. O'DELL: Object to the form.

8 A. I'd need to take a closer look
9 at the monograph, if you don't mind.

10 BY MR. ZELLERS:

11 Q. Are you aware of any human
12 studies linking the use of eugenol to any
13 type of cancer?

14 MS. O'DELL: Object to form.

15 A. I need to take a --

16 THE REPORTER: Was there an
17 objection? I couldn't hear you.

18 MS. O'DELL: Yes.

19 BY MR. ZELLERS:

20 Q. When you're ready, I'd like to
21 direct you to --

22 A. I'm still looking at the
23 monograph. Sorry.

24 So they found incidences of

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1 monograph.

2 Q. If you --

3 A. Endometrial stromal polyps were
4 observed in treated females.

5 Q. Mice. Correct?

6 A. Rats.

7 Q. Rats. That's what you see in
8 your --

9 A. Yeah, that's --

10 Q. -- evaluation of the IARC
11 monograph. Right?

12 A. Yeah. That's on Page 84. And
13 that's part of the female reproductive
14 system.

15 Q. Do you know the dose of eugenol
16 those animals -- those rats were exposed to?

17 A. It was USP grade eugenol, so
18 greater than 99 percent purity at
19 concentrations of -- it looks like 3,000 to
20 6,000 migs per kg of diet for 103 weeks.

21 There's also a skin application study here on
22 mice that I want to take a quick look at.

23 So 19 mice had papillomas, three
24 had carcinomas following dermal application,

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1 hepatocellular carcinoma in males in an oral
2 administration study.

3 Q. In human males?

4 A. In mice.

5 Q. Right. My question to you is:
6 There are no human studies that were
7 identified by IARC linking the use of eugenol
8 to any type of cancer. Correct?

9 MS. O'DELL: Object to the form.

10 A. I'm looking. Is there a section
11 on human? Because I haven't found it yet.

12 BY MR. ZELLERS:

13 Q. If you take a look at the
14 monograph, Exhibit 29, go to Page 89, 4.3,
15 human data, states -- and this is the --

16 A. Yep.

17 Q. -- IARC monograph.

18 A. That's correct. There is no
19 human data.

20 Q. With respect to animal studies,
21 the only potential association that has been
22 found relates to liver tumors. Is that
23 right?

24 A. I would need to check that

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1 and that was 0.1 -- sorry -- 150 micrograms.
2 IP administration, which is
3 intraperitoneal, group of mice there, the
4 study was -- no incidence of tumors in that
5 one.

6 They also looked at metabolites,
7 which is also done --

8 Q. Okay. Doctor, I've not asked
9 you anything about metabolites. I asked you
10 about human studies. I asked you about
11 animal studies.

12 MS. O'DELL: Well, he's talking
13 about the animal studies, so that's a
14 fair response. I mean, if you can
15 finish your answer, sir.

16 A. Yeah. And metabolites are
17 considered. Right? I mean, what the body
18 turns it into matters, so --

19 BY MR. ZELLERS:

20 Q. Okay, Doctor. I want to finish,
21 so please finish your answer and let me ask
22 my next question.

23 A. So --

24 MS. O'DELL: Finish your answer

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1 if you --
2 A. Yeah. I mean, each of these
3 IARC monographs needs to be considered in
4 whole, not just which parts suit your
5 position, that the absence of human studies
6 means that somehow these are safe. That's
7 not the conclusion that a person of skill in
8 the art would conclude.

9 So there were carcinogenicity
10 studies on the metabolites, and other
11 bio-relevant factors are considered.

12 BY MR. ZELLERS:

13 Q. You're referring to the animal
14 study in rats. Is that right?

15 A. Mice, rats, guinea pigs. They
16 did IV admin of multiple different doses in
17 dogs. All of that is considered when these
18 monographs are generated.

19 Q. And after all of that analysis
20 and after all of that review, the IARC expert
21 panel determined that eugenol was a Group 3
22 agent that was not classifiable as to its
23 carcinogenicity to humans. Correct?

24 A. That was the conclusion, yeah.

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1 the same -- so this is from 101. Mine is

2 also 101. Yeah.

3 BY MR. ZELLERS:

4 Q. We're in sync?

5 A. Yeah. Mine -- you know, again,
6 I think you've got snips here. You've only
7 got a few pages of the entire report.

8 Q. You, though, have the full
9 report on --

10 A. I do.

11 Q. -- your computer. Is that
12 right?

13 A. I do.

14 Q. IARC has classified benzophenone
15 as a 2B chemical. Is that right?

16 A. I believe so.

17 Q. 2B, according to IARC, means the
18 agent is possibly carcinogenic to humans. Is
19 that right?

20 A. Yes, 2B means possibly
21 carcinogenic to humans.

22 Q. It's true, is it not, that there
23 are no human studies linking the use of
24 benzophenone to any type of cancer. Correct?

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1 Q. Let me --

2 A. And the conclusion in the
3 monograph actually states it very clearly as
4 to why they drew that conclusion. It says,
5 "The evaluation is there is limited evidence
6 for carcinogenicity of eugenol in
7 experimental animals. In the absence of
8 epidemiological data, no evaluation can be
9 made of the carcinogenicity of eugenol in
10 humans."

11 Q. Let me ask you now about
12 benzophenone. That is the last agent that
13 you cite or reference IARC as a source for
14 its carcinogenicity. Is that right?

15 A. I think I also cited the
16 national -- the NTP technical report, which
17 is 267 pages long, and --

18 Q. Take a look at --

19 A. -- the IARC monograph.

20 Q. All right. Take a look, if you
21 will, at the IARC monograph, the excerpts,
22 relating to benzophenone, Exhibit 30.

23 (Exhibit No. 30 marked)

24 A. Yeah. It looks like we've got

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1 MS. O'DELL: Object to the form.

2 A. Yeah, the IARC monograph says no
3 data were available to the working group.

4 BY MR. ZELLERS:

5 Q. With respect to animal studies,
6 benzophenone exposure has only been
7 associated with an increased incidence of
8 hepatocellular cancer, histiocystic sarcoma,
9 leukemia, and renal tubal adenoma. Correct?

10 A. Let's see here. Hepatoblastoma
11 in male mice, histiocystic sarcoma in
12 females -- female mice, increased incidence
13 of mononuclear cell leukemia in male and
14 female rats. Renal tube adenoma in male
15 rats, histiocystic sarcoma in female rats, and
16 tumors in the kidney, yeah.

17 Q. There are no animal studies
18 linking the use of benzophenone with an
19 increased risk of ovarian cancer. Correct?

20 MS. O'DELL: Object to the form.

21 A. Just a moment. There's more
22 because don't forget there's an NTP report,
23 too. And, frankly, NTP is extraordinarily
24 thorough. So let's go look at that.

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<p>1 So according to the National 2 Toxicology Program, male rats receiving 3 benzophenone had severe kidney nephropathy, 4 kidney tumors, and leukemia. Female rats had 5 higher rates of leukemia, liver tumors, 6 increased severities of kidney nephrology, 7 metaplasia, epithelia of the nose and 8 hyperplasia of the spleen. Some female mice 9 also developed rare histiocytic sarcomas. I 10 believe those were associated with the 11 repro- -- female reproductive organs. 12 The NTP program also concluded 13 that benzophenone caused cancer -- kidney 14 cancer in male rats, liver tumors in male 15 mice, and histiocytic sarcomas in female 16 mice. 17 BY MR. ZELLERS: 18 Q. At least based upon the 19 information you have available to you and 20 that you're reading from, there is not an 21 animal study cited by NTP that associates 22 benzophenone in animals with an increased 23 risk of ovarian cancer. Correct? 24 A. Yeah, so, you know --</p>	<p>Page 278</p> <p>1 feed study controls, and the incidence in the 2 625 part per million group exceeded the 3 historical control range for all routes. 4 In the current two-year study, 5 only females were affected, and the liver and 6 lung were involved in all affected females. 7 The histiocytic sarcomas were 8 highly invasive in all three 1,250 PPM mice. 9 Multiple organs throughout the body had 10 neoplastic histiocytic legions; ovaries, 11 uterus, spleen, adrenal gland, kidney, 12 urinary bladder, and multiple lymph nodes 13 were affected in all three animals. 14 MR. ZELLERS: Move to strike as 15 nonresponsive. 16 BY MR. ZELLERS: 17 Q. Doctor -- 18 MS. O'DELL: I oppose the 19 motion. 20 BY MR. ZELLERS: 21 Q. On Page -- 22 THE REPORTER: I did not hear 23 you. 24 MS. O'DELL: I oppose the</p>
<p>1 Q. Is that correct? 2 A. That's correct, but the question 3 really requires some qualification. There is 4 no ovarian cancer animal model that I am 5 aware of. And if you look in the report 6 issued by Canada and their health ministry, 7 they state that. There is no animal model 8 for ovarian cancer. 9 Q. Are you ready for my next 10 question? 11 A. Yes. Just one moment, please. 12 You were asking about 13 benzophenone, and I knew there was an 14 association with ovaries. So this is from 15 the NTP report, and I'm going to read it. 16 Histiocytic sarcoma in females. There was a 17 positive trend in the incidence of 18 histiocytic sarcomas, all organs. The 19 evidence in 625 part per million females was 20 significantly greater than that in the 21 controls. 22 That's from Table 17 in D3 of 23 that particular report. Only two histiocytic 24 sarcomas have been observed in historical</p>	<p>Page 279</p> <p>1 motion. 2 BY MR. ZELLERS: 3 Q. On Page 21, you state that the 4 Environmental Protection Agency designated 5 p-Cresol, or para-Cresol, as possibly 6 carcinogenic. Is that right? 7 A. Yes. 8 Q. Do you know what studies the EPA 9 reviewed in determining that p-Cresol is a 10 potential carcinogen? 11 A. I believe that I found a report 12 to support that, and it was the -- also in 13 the NTP report. I also found "The tumor- 14 promoting -- tumor-promoting action of phenol 15 and related compounds" -- 16 THE REPORTER: Doctor. 17 THE WITNESS: I'm sorry. 18 THE REPORTER: I don't know if 19 I'm going to have that, so can you try 20 to read a little slower? 21 THE WITNESS: Yeah. 22 A. The report titled "The 23 tumor-promoting action of phenol and related 24 compounds for mouse skin" by Boutwell and</p>

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1 Bosch.
 2 Q. Again, you're referencing animal
 3 studies. Correct?
 4 A. Yeah.
 5 Q. You are not aware of any human
 6 studies relating p-Cresol as a potential
 7 carcinogen. Correct?
 8 MS. O'DELL: Object to the form.
 9 A. Just so we're clear, it's
 10 unethical to infuse human ovaries with
 11 para-Cresol or any of these. That's just not
 12 done.

13 BY MR. ZELLERS:

14 Q. The answer to my question is,
 15 yes, it's correct, you are not aware of any
 16 human studies. Right?

17 MS. O'DELL: No. Object to the
 18 form. You don't get to rephrase his
 19 answer.

20 MR. ZELLERS: I'm not --

21 MS. O'DELL: He responded to
 22 your question. If you want to ask him
 23 another question, Dr. Crowley is --

24 MR. ZELLERS: I want him to

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1 studies are done in animals.
 2 Q. Do you know whether
 3 carcinogenicity with p-Cresol has been
 4 observed in humans?
 5 MS. O'DELL: Object to the form.
 6 A. I'm sorry. Can you please
 7 repeat the question?
 8 BY MR. ZELLERS:
 9 Q. Sure. Are you aware of any
 10 study or finding of carcinogenicity observed
 11 in humans with p-Cresol or para-Cresol?
 12 MS. O'DELL: Object to the form.
 13 A. So I have a journal article here
 14 that I believe I cited, "The International
 15 Journal of Toxicology," from 2006, Volume 25,
 16 Supplement 1, Pages 29 through 127. "The
 17 safety of Cresols was reviewed by the World
 18 Health Organization in 1995. The WHO report
 19 concluded there is clear evidence in humans
 20 that during dermal or oral exposure, high
 21 concentrations of Cresols are corrosive,
 22 absorb rapidly, and produce severe toxicity
 23 that may result in death."

1 answer my --

2 MS. O'DELL: -- willing to
 3 respond to you. But you don't get to
 4 dictate what his response is going to
 5 be.

6 MR. ZELLERS: But I do get to
 7 ask him for a response.

8 MS. O'DELL: And he gave you
 9 one.

10 MR. ZELLERS: Well --

11 BY MR. ZELLERS:

12 Q. Doctor, you are not aware of any
 13 human study associating p-Cresol with any
 14 type of ovarian cancer. Correct?

15 MS. O'DELL: Object to the form,
 16 asked and answered.

17 A. So, as I said, I don't think
 18 that any regulatory authority in the world
 19 would allow me to administer para-Cresol to a
 20 human ovary. It wouldn't happen.

21 BY MR. ZELLERS:

22 Q. Are you --

23 A. So to make that assertion in
 24 humans is not ethically possible. These

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1 BY MR. ZELLERS:
 2 Q. Is there --
 3 A. So --
 4 Q. -- any study that associates
 5 p-Cresol or para-Cresol with ovarian
 6 cancer in humans?
 7 A. That study would never be done.
 8 So, no, that doesn't exist. It is unethical
 9 to dose ovaries with para-Cresol.
 10 Q. Are you aware of any observation
 11 of an increased risk of ovarian cancer with
 12 exposure to para-Cresol or para-Cresol in
 13 humans?
 14 MS. O'DELL: Object to the form.
 15 A. So I believe I mentioned this
 16 before. There was a positive validated
 17 cytogenic response in Chinese hamster ovary
 18 cells, including DNA damage to human
 19 lymphocytes, and morphological
 20 transformations in mouse fibroblasts.
 21 All three of those studies are
 22 done with cell lines. They are in vitro,
 23 because we don't ethically endanger humans,
 24 and those are all types of things that are

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1 considered by IARC, NTP, and so forth.

2 According to this report, Derek
3 and Lewis studied the cellular toxicity
4 effects against CHO cells in a culture for 20
5 hours with para-Cresol at a concentration
6 of 1,000 micrograms per mil, and they -- they
7 found these results, which are indicative of
8 toxicity.

9 BY MR. ZELLERS:

10 Q. You do not know the
11 concentration or the amount of p-Cresol or
12 para-Cresol in baby powder or Shower to
13 Shower. Correct?

14 MS. O'DELL: Object to the form.

15 A. Again, Johnson & Johnson never
16 provided the information in order to do any
17 kind of analysis like that.

18 BY MR. ZELLERS:

19 Q. You also have not made any
20 estimate or evaluation and have no
21 information as to the exposure of women to
22 either baby powder or Shower to Shower.
23 Correct?

24 MS. O'DELL: Object to the form.

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1 but we could go check the underlying study.

2 Q. What evidence are you relying on
3 that this molecule is associated with ovarian
4 cancer?

5 A. Let's go take a look. So sister
6 chromatid exchange and chromosomal
7 aberrations in Chinese hamster ovary cells,
8 the concentration was 16 to 160 micrograms
9 per milliliter in the Galloway study.

10 Let's go take a look at the
11 European Food Safety Authority studies if you
12 like.

13 Q. Any human study or study of
14 ethyl methylphenylglycidate --

15 A. Human tox studies aren't
16 performed, as we've discussed.

17 Q. So the answer is no. Correct?
18 No human toxicology study. Correct?

19 MS. O'DELL: Object to the form.

20 A. That's correct.

21 BY MR. ZELLERS:

22 Q. Juniperus communis fruit oil.
23 You state that the CIR expert panel concluded
24 that there is insufficient information

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1 A. Yeah, so I can't do that without
2 the information that Johnson & Johnson did
3 not provide, so --

4 BY MR. ZELLERS:

5 Q. On Page 21 of your report, you
6 state that the European Food Safety Authority
7 found that there is substantial evidence that
8 ethyl methylphenylglycidate --

9 A. I'm sorry. What page did you
10 say?

11 Q. Page 21 -- has genotoxic
12 potential from the available in vitro and
13 in vivo studies.

14 Did you make that statement?

15 A. I didn't make that statement.

16 The European Food Safety Authority did.

17 Q. Do you know whether these
18 studies were conducted on animals or humans?

19 A. Usually those studies are
20 conducted on animals.

21 Q. Do you know what doses of the
22 chemical the study subjects, the animals,
23 were exposed to?

24 A. I didn't commit them to memory,

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1 available to support the safety of juniperus
2 communis fruit oil for use in cosmetics.

3 Did you make that statement?

4 A. I believe I quoted the CIR
5 review panel.

6 Q. Do you know what --

7 A. So it's not really a statement.

8 It's -- it's a citation to those folks.

9 Q. Do you know what information the
10 CIR expert panel considered?

11 A. Yeah, I read the report.

12 Q. Do you know if it was related to
13 any type of cancer?

14 A. I would have to go back and
15 review the report.

16 Q. Juniperus communis fruit oil is
17 fruit oil. Correct?

18 A. It's juniper fruit oil, I
19 believe, which -- I mean, it's a -- it's an
20 extract. Right? So I think, actually,
21 that's one that's actually a combination of
22 many things. I don't think it's one unique
23 chemical, if my memory serves me.

24 Q. On Page 48, you state that the

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<p style="text-align: right;">Page 290</p> <p>1 European Scientific Committee on Health and 2 Environmental Risk has classified musk ketone 3 as a Category 3 carcinogen. Is that right? 4 A. I'm sorry. What page did you 5 say?</p> <p>6 Q. Page 48. 7 A. Again, I didn't state it. I'm 8 just citing the source.</p> <p>9 Q. You went out and you did your 10 search and collected information, and here 11 you're citing from an entity called SCHER, 12 S-C-H-E-R, which is the Scientific Committee 13 on Health and Environmental Risk with the 14 European Commission. Is that right?</p> <p>15 A. Yes. 16 (Exhibit No. 31 marked)</p> <p>17 BY MR. ZELLERS:</p> <p>18 Q. Take a look at Deposition 19 Exhibit 31. This document sets forth the 20 classification of a musk ketone. Is that 21 right? And again --</p> <p>22 A. Yep. 23 Q. Strike that. 24 Turning to the third page in the</p>	<p style="text-align: right;">Page 292</p> <p>1 assessment. 2 So this is consistent with how I 3 have worked in the past in doing safety 4 analyses on other compounds. 5 BY MR. ZELLERS: 6 Q. What the Scientific Committee on 7 Health and Environmental Risk looked at was a 8 chemical called musk xylene. Is that right? 9 A. That's what it says. 10 Q. If you take a look at the 11 information that they considered in 12 classifying musk ketone as a Category 3 13 carcinogen -- look on Page 3, under opinion, 14 the second paragraph of 3.1, introduction. 15 Do you see that? 16 A. Yes. 17 Q. What SCHER -- the committee 18 states, "Musk xylene has been classified as 19 'Category 3 carcinogen'" -- 20 A. Uh-huh. 21 Q. -- "based on an 80-week oral 22 carcinogenicity study in mice and absence of 23 genotoxicity. The classification of musk 24 xylene as 'Category 3 carcinogen' is</p>
<p style="text-align: right;">Page 291</p> <p>1 second paragraph under background, it states, 2 "The recommendation for carcinogenic 3 Category 3 was obtained by reading-across 4 from musk xylene (which is classified as such 5 since the 29th ATP), since there are no test 6 data on carcinogenicity on musk ketone 7 itself."</p> <p>8 Is that right?</p> <p>9 A. That's right.</p> <p>10 Q. So the classification was based 11 on studies of a chemical that is similar to 12 musk ketone, but not on studies that actually 13 involved musk ketone. Correct?</p> <p>14 MS. O'DELL: Objection to form.</p> <p>15 A. That's correct. And you make 16 a -- this is, I think, an important 17 circumstance here. Because this is how the 18 SafeBridge folks classify compounds. They do 19 a read-across.</p> <p>20 What does this particular 21 compound have in common with others that are 22 like it? And as part of that, they examine 23 the available literature in animal studies 24 and in vitro studies to make that sort of</p>	<p style="text-align: right;">Page 293</p> <p>1 considered as a borderline case since an 2 increase in liver tumors in the highly 3 sensitive B6C3F1 mouse is considered of 4 little relevance for human hazard 5 assessment." 6 Did I read that correctly? 7 A. Yes, I believe you did. 8 Q. All right. Musk xylene is 9 classified as a Category 3 carcinogen based 10 on this study of mice. Correct? 11 A. Well, I mean, you just read the 12 paragraph to me. It's an 80-week oral study. 13 Now, in this -- in this case, I'd like to see 14 an 80-week vaginal study. 15 Q. Okay. You've got to answer -- 16 please answer my questions. 17 This classification was based 18 upon an animal study; in this case, mice. Is 19 that correct? 20 A. Yes. 21 Q. The mice were highly predisposed 22 to cancer. Is that right? 23 A. I mean, they said highly 24 sensitive. I don't know that that means</p>

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1 they're predisposed or not, but --

2 Q. This animal study does not
3 relate in any way to ovarian cancer.
4 Correct?

5 A. I wouldn't --

6 MS. O'DELL: Object to the form.

7 THE WITNESS: Sorry.

8 A. Yeah, I wouldn't call it that.

9 BY MR. ZELLERS:

10 Q. You would agree with me that it
11 doesn't relate to ovarian cancer?

12 A. No, not really. No.

13 MR. ZELLERS: Let's take a break
14 so we can change our disc.

15 THE WITNESS: Okay.

16 THE VIDEOGRAPHER: Going off the
17 record, the time is 4:01 p.m.

18 (Recess from 4:01 p.m. to

19 4:21 p.m.)

20 THE VIDEOGRAPHER: This marks
21 the beginning of Disc 4. Back on the
22 record, the time is 4:21 p.m.

23 BY MR. ZELLERS:

24 Q. Dr. Crowley, I want to go back

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1 only thing I want to clarify is that you and
2 I were in agreement that at least with musk
3 xylene, there was no animal study associating
4 that chemical or musk ketone with ovarian
5 cancer. Correct?

6 A. That's correct.

7 Q. All right.

8 A. It's got similar properties to
9 musk xylene, but it does not have
10 carcinogenic studies in animals.

11 Q. In your report, Section 4.4, you
12 discuss the fragrance chemicals that are
13 classified as irritants. Is that right?

14 This is Page 27.

15 A. I think so, yes.

16 Q. You rely on hazard statements
17 from the GHS. Is that right?

18 A. GHS and -- and OSHA.

19 Q. You have a discussion here about
20 whether the GHS classifies the chemical as an
21 irritant or sensitizer. Is that right?

22 A. I'm sorry. What's your --
23 what's your question?

24 Q. Sure. My question is --

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1 just to the Deposition Exhibit 31. I thought
2 I asked you a couple of questions at the end
3 of our last session which were clear, but
4 when I glanced back at our real-time
5 transcript, they did not look clear.

6 MS. O'DELL: The last exhibit I
7 have is 30. Am I wrong?

8 THE WITNESS: It's the musk
9 ketone.

10 MS. O'DELL: Musk ketone.

11 Excuse me. Okay. Sorry.

12 BY MR. ZELLERS:

13 Q. My only question that I want to
14 clarify is we had some discussion about a
15 study involving mice and musk xylene. That
16 study did not -- was an animal study, but it
17 did not relate in any way to ovarian cancer.
18 Is that correct?

19 MS. O'DELL: Object to the form.

20 A. Yeah. I mean, that was a --
21 where was it? I'm sorry. We were on Page 3.
22 Where was the dadgum thing? It was --

23 BY MR. ZELLERS:

24 Q. I was looking on Page 3. The

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1 A. Are you asking me if I described
2 them? Yes, I did.

3 Q. All right. GHS also has

4 classifications for the carcinogenicity of

5 chemicals. Is that right?

6 A. I believe so, yes.

7 Q. Those categories are H350, may
8 cause cancer; H350i, may cause cancer by
9 inhalation; and H351, suspected of causing

10 cancer?

11 MS. O'DELL: Object to the form.

12 BY MR. ZELLERS:

13 Q. Is that right?

14 A. That is consistent with my
15 recollection. I think they may have a few
16 more, but I could be wrong. I'd have to look
17 at it.

18 Q. The GHS, to your knowledge, has
19 not classified any of these chemicals as may
20 cause cancer or suspected of causing cancer.
21 Correct?

22 MS. O'DELL: Object to the form.

23 A. I don't believe that I looked
24 for that.

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<p>1 BY MR. ZELLERS:</p> <p>2 Q. Are you aware of any 3 classification by GHS with respect to any of 4 the chemicals that you identify in your 5 report where GHS has classified the chemicals 6 as either may cause cancer or suspected of 7 causing cancer?</p> <p>8 A. I think there were --</p> <p>9 MS. O'DELL: Object to the form, 10 asked and answered.</p> <p>11 THE WITNESS: Sorry.</p> <p>12 A. I think there were some that 13 were marked as suspected, and they --</p> <p>14 BY MR. ZELLERS:</p> <p>15 Q. Are those in your report?</p> <p>16 A. I believe they're in the 17 appendices. I think I put them in there. Do 18 you want me to search for them?</p> <p>19 Q. No. What I want you to do, 20 though, is -- you collected this information 21 regarding the different chemicals. Correct?</p> <p>22 A. Yes.</p> <p>23 MS. O'DELL: Object to the form.</p> <p>24</p>	<p>Page 298</p> <p>1 information is a predecessor to the GHS 2 system. Correct?</p> <p>3 MS. O'DELL: Object to the form.</p> <p>4 A. I don't know which came first, 5 to be candid with you, so --</p> <p>6 BY MR. ZELLERS:</p> <p>7 Q. They contain similar type 8 information?</p> <p>9 A. Yeah.</p> <p>10 Q. What methodology did you use to 11 determine that chemicals that GHS classifies 12 as irritants or sensitizers but not 13 carcinogens contribute to cancer?</p> <p>14 MS. O'DELL: Object to the form, 15 mis- -- lack of foundation.</p> <p>16 A. So, you know, as I was stating 17 previously, irritants, sensitizers, 18 allergens, and so forth all elicit immune 19 responses -- I'm sorry -- inflammatory 20 responses, and increases in inflammation have 21 been associated with a higher risk for 22 cancer.</p> <p>23 BY MR. ZELLERS:</p> <p>24 Q. For each of the chemicals that</p>
<p>1 BY MR. ZELLERS:</p> <p>2 Q. That would have included any GHS 3 assessments of the chemicals, including 4 whether they may cause cancer or are 5 suspected of causing cancer. Correct?</p> <p>6 A. No. I looked at MSDS sheets, 7 and I also looked at fragrance companies that 8 had some of that information on their 9 websites.</p> <p>10 So the -- if I found the 11 information in an MSDS, I recorded it. If it 12 was listed on the fragrance company website, 13 you know, I recorded that as well.</p> <p>14 I didn't buy access to the GHS 15 system that has those listings for each and 16 every chemical. I don't know how to do -- 17 how to get that access, so --</p> <p>18 Q. To the extent you found any 19 information, you would have included it in 20 your --</p> <p>21 A. Yes.</p> <p>22 Q. -- appendices. Correct?</p> <p>23 A. Yes.</p> <p>24 Q. MSDS, those sheets or that</p>	<p>Page 299</p> <p>1 you list in Section 4.4 that are classified 2 as irritants, do you know how much exposure 3 is necessary to cause irritation?</p> <p>4 MS. O'DELL: Object to the form.</p> <p>5 A. It varies on a case-by-case 6 basis. I did make every effort to identify 7 and find those underlying studies, including 8 studies that were published, you know, 70 9 years ago in the 1950s. Many of those 10 studies were included in the fragrance 11 monograph book that I purchased that outlined 12 them that described the thresholds.</p> <p>13 And, in addition, several of 14 these compounds, as we talked about 15 previously, have usage restrictions described 16 by any number of authorities like the 17 European Food Safety Authority or the FDA. 18 And then, you know, the trade groups, you 19 know, IFRA and CIR have also, you know, 20 published levels.</p> <p>21 BY MR. ZELLERS:</p> <p>22 Q. With irritants, threshold levels 23 or dosage is a necessary part of the 24 analysis. Correct?</p>

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1 MS. O'DELL: Object to the form.
2 A. Yes. Irritants are threshold
3 based. You know, the important thing to
4 understand there is it's usually done on a
5 fairly small pool of people, and the
6 threshold is sort of an average of a group,
7 so it may vary from person to person.
8 BY MR. ZELLERS:

9 Q. As we discussed earlier, you did
10 not consider how much of each chemical is in
11 the finished product, either baby powder or
12 Shower to Shower. Correct?

13 MS. O'DELL: Object to the form.
14 A. So we -- we've talked about this
15 a lot. We asked for the information from J&J
16 to enable doing that, and it was never
17 provided. So I was unable to do that kind of
18 thing.

19 BY MR. ZELLERS:

20 Q. You did not consider how much of
21 each chemical actually reached the ovary in
22 women. Correct?

23 MS. O'DELL: Object to the form.
24 A. Yeah, I've answered that

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1 and then the GHS classifications; H315,
2 causes skin irritation; H317, causes an
3 allergic skin reaction; R 36/38, irritating
4 the skin and eyes; R 43 --

5 THE REPORTER: Skin what?
6 Irritating the skin --
7 THE WITNESS: And eyes.
8 THE REPORTER: You're facing
9 that way. Thank you.

10 Q. If you make reference to a GHS
11 classification in the appendices, you had
12 access, then, to the GHS classifications for
13 that chemical. Correct?

14 MS. O'DELL: Object to the form.

15 A. I got the information from a
16 number of sources. So MSDS sheets, fragrance
17 company websites, the -- a number of sources,
18 including the monograph of fragrance and
19 flavors also had some of those.

20 So, you know, if it's been
21 disclosed as an irritant or a skin sensitizer
22 but I was unable to find, you know, an MSDS
23 that stated it as such -- you know, so, for
24 example, I think that -- I mean, the balsam

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1 question previously.

2 BY MR. ZELLERS:

3 Q. And that was not information
4 that you had available. Correct?

5 MS. O'DELL: Object to the form.

6 A. I wasn't asked to consider it,
7 and it wasn't available to me.

8 BY MR. ZELLERS:

9 Q. And at least on how much of a
10 chemical may reach the ovary, you'll defer to
11 other experts. Is that correct?

12 MS. O'DELL: Object to the form.

13 A. Yeah, potentially. I may get
14 reengaged to provide more testimony there.

15 BY MR. ZELLERS:

16 Q. What studies are you relying on
17 in classifying these chemicals in Section 4.4
18 as irritants? Are they referenced in your
19 report?

20 A. Yeah, they're predominantly
21 listed in the appendices. So, for example,
22 if you go to Page 70, that's the Appendix A,
23 and it starts with d-Limonene. You'll see
24 that the fourth column there's a PubChem link

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1 Peru, one of the reasons it's restricted is
2 because so many people are sensitive to it.
3 I didn't need a GHS to know that it was a
4 sensitizer.

5 BY MR. ZELLERS:

6 Q. My question is a little
7 different.

8 If you reference a GHS
9 category --

10 A. Yeah.

11 Q. -- for a chemical in your
12 appendix, does that mean, for that chemical,
13 that you had access to the GHS data?

14 A. No. So you're asking did I look
15 at the underlying data from an MSDS sheet?
16 Not necessarily.

17 You know, I did a literature
18 review. I used Web of Science. I used
19 Google Scholar. You know, a number of these
20 sources, including that monograph book,
21 provide the underlying data that you can go
22 to.

23 And so I cited that where
24 possible inside the report and in the

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1 appendices, and in many cases I did go read
2 the underlying reports if I could get them.

3 Q. Do you know whether, in the
4 reports that you looked at, that there was a
5 pure concentration of the substance used or a
6 diluted chemical?

7 MS. O'DELL: Objection to the
8 form.

9 A. Yeah, almost always in the early
10 studies they were mixing it with Vaseline and
11 diluting it. And they, in some cases, would
12 do multiple strengths. They were not
13 applying it at a 100 percent concentration,
14 nor were they applying it after it had been
15 blended with talc.

16 So the utility of those, you
17 know, studies could certainly vary. There
18 could be, certainly, instances where, you
19 know, blending with talc reduces the
20 likelihood of irritation or sensitization or
21 an allergic response, and, to the contrary,
22 there may be circumstances where blending
23 with talc could produce a stronger irritation
24 or what have you.

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1 MS. O'DELL: Object to the form.
2 A. I have found studies that link
3 inflammation to cancer. That's an
4 established link. That's indisputable. The
5 Canadians stated as much in their assessment
6 on peroneal application of talc, and these
7 fragrance chemicals are part of that product.
8 BY MR. ZELLERS:

9 Q. How --
10 A. It's all -- it's all part of one
11 product.

12 Q. How do you define inflammation?
13 A. An inflammatory response.
14 Q. How do the ingredients you
15 identify as irritants cause inflammation?

16 MS. O'DELL: Object to the form.
17 A. I can't believe I'm going to
18 have to explain how an irritant causes
19 inflammation.
20 Inflammation is the result of
21 any number of insults to a tissue. Cell
22 death results in inflammation just as much as
23 a burn does. So there's all sorts of
24 chemicals, including cytokines and so forth,

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1 BY MR. ZELLERS:

2 Q. Those types of studies or
3 information was not available to you.
4 Correct?

5 MS. O'DELL: Objection to form.

6 A. No. Some of them were. I did
7 go look at several of them.

8 BY MR. ZELLERS:

9 Q. And you referenced them in the
10 appendices. Is that right?

11 A. Yeah.

12 Q. You have not done any scientific
13 analyses yourself as to whether or not a skin
14 or eye irritant can cause or contribute to
15 ovarian cancer in humans. Correct?

16 MS. O'DELL: Object to the form.

17 A. I have not done that study.

18 BY MR. ZELLERS:

19 Q. You also have not found any
20 studies on humans that support the statement
21 that irritation can lead to inflammation and
22 can contribute to ovarian cancer with respect
23 to the chemicals you identify as irritants.
24 Is that right?

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1 associated with inflammation. It's so well
2 understood, you can draw blood and mesh
3 concentrations in plasma and get a sense of
4 how inflamed someone is.

5 BY MR. ZELLERS:

6 Q. At what dose does an irritant
7 cause inflammation?

8 MS. O'DELL: Object to the form.

9 A. That varies on a case-by-case
10 basis.

11 BY MR. ZELLERS:

12 Q. As we discussed earlier, you
13 have not done any type of dose analysis with
14 respect to the chemicals or fragrance
15 chemicals that you have identified in the
16 baby powder or Shower to Shower. Correct?

17 MS. O'DELL: Object to the form.

18 A. Yeah, I was unable to do it
19 because J&J didn't provide the information to
20 enable such an analysis.

21 BY MR. ZELLERS:

22 Q. In your opinion, do both acute
23 and prolonged inflammation contribute to
24 ovarian cancer?

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<p>1 A. That's my understanding, yes.</p> <p>2 Q. What study or studies are you 3 relying on for that statement?</p> <p>4 A. Okay. Ness and Cottreau from 5 1999 -- these are from Dydek's paper. I can 6 also point you to the Canadian assessment on 7 the safety of talc where they also stated 8 that chronic inflammation and oxidative 9 stress are important factors in the 10 development and behavior of cancer, including 11 ovarian cancer.</p> <p>12 But it might be better to rely 13 upon some of the other experts to address 14 that. But since you asked, I can list the 15 papers that I looked at.</p> <p>16 Q. Okay. I don't need you to read 17 me the papers that are referenced in 18 Dr. Dydek's report. That's what you're 19 referring to. Is that right?</p> <p>20 MS. O'DELL: Object to the form. 21 I don't think that's what he was -- he 22 was saying.</p> <p>23 A. No. I mentioned Dydek and the 24 Canadian Department of -- or Ministry of</p>	<p>Page 310</p> <p>1 A. 42?</p> <p>2 Q. Yes.</p> <p>3 MS. O'DELL: I don't think 4 that's the right page.</p> <p>5 MR. ZELLERS: We looked at this 6 earlier today. It was --</p> <p>7 BY MR. ZELLERS:</p> <p>8 Q. So on Page 42 for methyl 9 salicylate --</p> <p>10 A. Salicylate.</p> <p>11 Q. -- salicylate, you identify the 12 IFRA acceptable level of use in dermal 13 cosmetics, the amount. Is that right?</p> <p>14 A. I have listed the use level for 15 cosmetics and the dermal systemic exposure in 16 cosmetic products. There's two of them.</p> <p>17 Q. We had the discussion before. 18 You don't know the amount or the 19 concentration that is in the talc powder or 20 Shower to Shower product in this case.</p> <p>21 Correct?</p> <p>22 A. That's correct.</p> <p>23 MS. O'DELL: Object to the form.</p> <p>24</p>
<p>1 Health report.</p> <p>2 BY MR. ZELLERS:</p> <p>3 Q. Your methodology here, again, 4 was to go out and, you know, to do a search 5 of the literature and to read the literature 6 and to provide the opinions that you're 7 providing today. Correct?</p> <p>8 A. That was one part of it, yeah.</p> <p>9 Q. You've identified ingredients as 10 skin and eye irritants for which IFRA has 11 established acceptable levels of use. Is 12 that right?</p> <p>13 A. I'm sorry. What page are you 14 on?</p> <p>15 Q. Well, look at Page 30 of your 16 report, Table 8. You identify methyl 17 salicylate as a skin and eye irritant. Is 18 that right?</p> <p>19 A. Methyl salicylate, yeah.</p> <p>20 Q. Then on Page 42 of your report, 21 you show that IFRA has established acceptable 22 levels of use in dermal cosmetics.</p> <p>23 A. Sorry.</p> <p>24 Q. Is that --</p>	<p>Page 311</p> <p>1 BY MR. ZELLERS:</p> <p>2 Q. In your report, you opine that 3 the eye and the vagina are similar because 4 they are both mucous membranes. That's on 5 Page 12. Is that right?</p> <p>6 A. I think you've mischaracterized. 7 So most of these cosmetic chemicals have eye 8 irritation studies because a lot of them go 9 in cosmetics, so they end up near the eye. 10 And so the exposure to the eye is considered 11 as part of the safety program.</p> <p>12 Vaginal applications, not so 13 much, because very few cosmetics are applied 14 to the vaginal area. Usually those are 15 drugs.</p> <p>16 Q. You would agree, then, that the 17 eye and the vagina are not the same in terms 18 of mucous membranes and any irritation from 19 the chemicals you've identified?</p> <p>20 MS. O'DELL: Object to the form.</p> <p>21 A. They are both mucous membranes, 22 and what I've suggested is that which 23 irritates the eye is also very likely to 24 irritate the vagina. The difficulty proof</p>

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<p>1 would be to do that study, but, again, there 2 are some ethics involved in that. 3 BY MR. ZELLERS: 4 Q. What study are you relying on to 5 make the statement that fragrances that are 6 identified as eye irritants are likely to 7 irritate the vaginal mucosa? 8 A. It's common general knowledge. 9 The same thing -- I mean, the same thing -- 10 usually those that irritate eyes also 11 irritate lungs. They're both mucous 12 membranes. Not always, but it's a good and 13 safe generalization. 14 Q. Are there studies that you are 15 aware of with respect to the irritation of 16 the chemicals that you identified in your 17 report as irritants to the vaginal mucosa? 18 A. I would have to check. I think, 19 like I said, I found three out of the 175 20 that have been studied in the -- for safety 21 in the vagina. So only three out of the 175 22 have been examined in those studies. I'd 23 need to go check and find out if any of them 24 were found to be vaginal irritants.</p>	<p>Page 314</p> <p>1 cause inflammation and oxidative stress. 2 Q. Are you aware of any studies 3 which have looked at the use of sensitizers 4 in the development of ovarian cancer? 5 MS. O'DELL: Object to the form. 6 A. To the best of my knowledge, 7 there is no good animal study for ovarian 8 cancer. So I kind of feel like we keep 9 getting some of the same questions to which I 10 feel like I've already answered. 11 Q. What -- 12 A. So -- 13 Q. Go ahead. Finish. 14 A. So, no, I don't think there are, 15 because there isn't a model that's 16 acceptable. 17 Q. What does sensitization have to 18 do with the development of cancer? 19 A. I just stated that sensitizers 20 can cause inflammation and oxidative stress, 21 which are associated with a greater risk of 22 cancer. 23 Q. Are you aware of any studies 24 relating to how sensitizers are related to</p>
<p>1 Q. If any were vaginal irritants, 2 that would be information in your appendices. 3 Correct? 4 A. Presuming I found that, yeah. 5 Q. As you sit here, you're not -- 6 you don't at least have a recollection of 7 having found that? 8 A. There was -- 9 MS. O'DELL: Object to the form. 10 A. Yeah, there was such little 11 information available on vaginal 12 administration of this, I don't recall that 13 any -- if any of them were vaginal irritants. 14 BY MR. ZELLERS: 15 Q. Sensitizers. In your report, 16 Section 4.5, you discuss the fragrance 17 chemicals that are classified as sensitizers. 18 Is that right? 19 A. Section 4.5 is on sensitizers, 20 that's right. 21 Q. What does sensitization have to 22 do with the development of ovarian cancer? 23 A. If you are exposed to a 24 sensitizer and you're sensitive to it, it can</p>	<p>Page 315</p> <p>1 the development of cancer in humans? 2 MS. O'DELL: Object to the form, 3 asked and answered. 4 A. I feel like I just answered that 5 question, so same answer. They cause 6 oxidation -- oxidative stress and 7 inflammation. 8 BY MR. ZELLERS: 9 Q. My question, though, is: Are 10 you aware of any studies that demonstrate 11 that, sensitizers and the development of 12 cancer? 13 A. I would have -- 14 MS. O'DELL: Asked and answered. 15 A. Yeah. I would have to provide 16 the same response, and I feel like I've 17 answered the question, so -- 18 BY MR. ZELLERS: 19 Q. And I don't -- 20 A. In humans? 21 Q. -- mean to be disrespectful -- 22 A. Are you asking in humans? 23 Q. In humans, yes. In humans, 24 you're not aware of any studies. Correct?</p>

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<p>1 A. You know, again, this is an 2 ethics question. I -- I don't think the FDA 3 would let me take, for example, Peru balsam 4 and, you know, gavage a female's ovaries. I 5 don't think that they would ever approve that 6 protocol, and I think if I did submit one to 7 them like that, I don't think any of my 8 subsequent protocols would ever be 9 considered.</p> <p>10 MR. ZELLERS: Move to strike as 11 nonresponsive.</p> <p>12 BY MR. ZELLERS:</p> <p>13 Q. My question simply was: Are you 14 aware of any human study of sensitizers and 15 the development of cancer?</p> <p>16 I believe your answer is "no." 17 Correct?</p> <p>18 A. No. You're not ethically 19 allowed to do that.</p> <p>20 Q. Are you aware of any studies? 21 MS. O'DELL: He just answered 22 it.</p> <p>23 MR. ZELLERS: What did he say, 24 Ms. O'Dell? What was his answer?</p>	<p>Page 318</p> <p>1 basis. Some of that information was made 2 available in the underlying data that I 3 looked at where they published the -- the 4 no-adverse-event level.</p> <p>5 I did find some where it varied 6 study to study. So it -- it, again, is -- is 7 information that was available in some of the 8 reports. Some of it, the underlying data 9 wasn't present.</p> <p>10 Q. The studies that you found for 11 each of the chemicals you referenced in the 12 appendices. Correct?</p> <p>13 A. Where I found them, yes, sir.</p> <p>14 Q. You did not make any 15 determination that a sensitizer can cause or 16 contribute to ovarian cancer in humans. Is 17 that right?</p> <p>18 MS. O'DELL: Object to the form, 19 asked --</p> <p>20 A. The same question that I've 21 answered previously. The same answer.</p> <p>22 BY MR. ZELLERS:</p> <p>23 Q. And the answer is "no." 24 Correct?</p>
<p>1 MS. O'DELL: His answer, "No. 2 You're not ethically allowed to do 3 that."</p> <p>4 MR. ZELLERS: All right. Is his 5 answer, no, there are no such studies?</p> <p>6 MS. O'DELL: I think he said, 7 "No," period, "You're not ethically 8 allowed to do that."</p> <p>9 MR. ZELLERS: Okay. If he 10 said --</p> <p>11 MS. O'DELL: I'm reading back 12 his answer from the court reporter.</p> <p>13 MR. ZELLERS: If he said, "No," 14 period, then I'm okay with that.</p> <p>15 MS. O'DELL: Do you need to 16 clarify that, Dr. Crowley?</p> <p>17 A. There are no studies because 18 you're not allowed to do the study.</p> <p>19 BY MR. ZELLERS:</p> <p>20 Q. Thank you. For each of these 21 chemicals, these sensitizers, do you know how 22 much exposure is necessary to cause 23 sensitization?</p> <p>24 A. It varies on a case-by-case</p>	<p>Page 319</p> <p>1 A. We can go back through my 2 testimony.</p> <p>3 Q. Well, I'm talking about --</p> <p>4 A. There are no studies --</p> <p>5 Q. Go ahead.</p> <p>6 A. There are no studies because 7 they are unethical.</p> <p>8 Q. What is the basis for your 9 opinion that chemicals that cause 10 sensitization cause inflammation?</p> <p>11 MS. O'DELL: Object to the form, 12 asked and answered.</p> <p>13 A. It's an insult to tissue or a 14 cell, and inflammation is a response as part 15 of that, as is, in many cases, oxidative 16 stress.</p> <p>17 BY MR. ZELLERS:</p> <p>18 Q. Section 4.6 of your report, you 19 discuss that -- the fragrance chemicals that 20 are classified as allergens. Is that right?</p> <p>21 A. Yep.</p> <p>22 Q. Allergens only produce a 23 response in individuals who are allergic to 24 the substance. Is that right?</p>

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<p>1 A. That's correct. 2 Q. You did not make any assessment 3 as to how much exposure is necessary to cause 4 an allergic response with these allergens. 5 Is that right? 6 MS. O'DELL: Object to the form. 7 A. Yeah. I couldn't do that 8 because J&J didn't provide the information, 9 as we've discussed. 10 BY MR. ZELLERS: 11 Q. Any studies that you're relying 12 on to classify these chemicals as allergens, 13 would they be referenced in your appendices? 14 A. Yes, where -- where identified, 15 yeah. 16 Q. You are not expressing an 17 opinion that exposure to an allergen can 18 cause or contribute to ovarian cancer. 19 Correct? 20 A. That's -- 21 MS. O'DELL: Object to the form. 22 A. Yeah, that's correct. I'm not 23 expressing that opinion. 24</p>	<p>Page 322</p> <p>1 studies that I looked at. 2 Q. If it was referenced in the 3 studies you looked at, you would include it 4 in your appendices? 5 A. I tried to, yeah. 6 Q. With respect to Shower to Shower 7 or baby powder, you did not make any 8 assessment as to whether there was sufficient 9 exposure to result in a critical effect. 10 Correct? 11 A. Yeah, I couldn't -- 12 MS. O'DELL: Object to the form. 13 A. I couldn't do that because I 14 didn't have the information from J&J to 15 enable to do that. 16 THE REPORTER: Try and keep your 17 voice up when giving your answer, 18 please. 19 THE WITNESS: Sorry about that. 20 BY MR. ZELLERS: 21 Q. As best you can tell, 22 phototoxicity is not related to ovarian 23 cancer. Correct? 24 A. I'm sorry. Say that again.</p> <p>Page 324</p>
<p>1 BY MR. ZELLERS: 2 Q. Section 4.7, you identify a 3 number of components that IFRA has designated 4 as having a critical effect. Is that right? 5 A. Yes. 6 Q. According to Table 11, those 7 critical effects are sensitization, dermal 8 sensitization, and phototoxicity. Correct? 9 A. There's also one with a 10 potential for nitrosamine formation. 11 THE REPORTER: I'm sorry. Say 12 it again. 13 THE WITNESS: Potential for 14 nitrosamine formation. 15 BY MR. ZELLERS: 16 Q. For each of these chemicals, do 17 you know how much exposure is necessary to 18 cause the given critical effect? 19 A. Are you asking about from baby 20 powder or Shower to Shower, or are you asking 21 about pure chemical? 22 Q. The first question is pure 23 chemical. 24 A. Yeah, some of that was in the</p>	<p>Page 323</p> <p>1 Q. Phototoxicity is not related to 2 ovarian cancer. Correct? 3 A. To the best of my knowledge, 4 yeah. 5 Q. IFRA Category 5 restriction, 6 Section 4.8, you identify a number of 7 components for which IFRA has established a 8 Category 5 restriction. Is that right? 9 A. Yes. 10 Q. That means IFRA has capped the 11 usage levels due to concerns about dermal 12 sensitization or allergic response. Is that 13 right? 14 A. I don't know that that's the 15 only two concerns that they cited in putting 16 these Category 5 caps in place, because 17 Category 5 includes not just baby powder and 18 talcs, but facial creams, facial makeup, hand 19 creams, facial masks, hair -- hair permanent. 20 I think there are a lot of factors. 21 Q. For each of these chemicals, do 22 you know how much exposure is necessary to 23 cause an allergic or sensitization response? 24 A. Again, it's case by case, and</p> <p>Page 325</p>

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1 the underlying information is, generally
2 speaking, available.

3 Q. You have no opinion, though,
4 with respect to any of these chemicals in
5 baby powder or Shower to Shower as to whether
6 or not there is a sufficient exposure to
7 cause an allergic or sensitization response.
8 Correct?

9 MS. O'DELL: Object to the form.

10 A. You know, if your client wants
11 to provide me that information, perhaps I
12 could make that judgment, but I don't have
13 it.

14 BY MR. ZELLERS:

15 Q. If IFRA relied on studies in
16 setting these Category 5 restrictions on the
17 chemicals you identify in your report, you
18 attempted to include that in your appendices?

19 MS. O'DELL: Object to the form.

20 A. Yes, I did.

21 BY MR. ZELLERS:

22 Q. Do you know whether the studies
23 that IFRA looked at on setting these
24 Category 5 restrictions were studies

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1 have been glued to talc particles,
2 administered to the peritoneal area, which
3 subsequently enters the vagina, and where
4 that talc particle goes, those fragrance
5 chemicals go with it. They have
6 demonstrated -- many of them -- demonstrated
7 biological activity in animal and in vitro
8 cell models that demonstrates toxicity and
9 carcinogenicity.

10 And so -- excuse me. I'm not
11 done yet. I don't know how else to state it.
12 I think they can absolutely contribute to the
13 carcinogenicity of the product in total.

14 BY MR. ZELLERS:

15 Q. In this section, in terms of the
16 carcinogenicity, you do not know or have any
17 information as to whether any of these
18 ingredients in Johnson's baby powder or
19 Shower to Shower exceed the IFRA
20 restrictions. Correct?

21 MS. O'DELL: Object to the form.

22 A. Yeah, I don't know because I was
23 never given the composition by Johnson &
24 Johnson.

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1 involving a pure concentration of the
2 substance or a diluted substance?

3 A. You know, it was both. I mean,
4 IFRA publishes a lot of these studies in
5 peer-reviewed journals, you know, as opposed
6 to CIR, which doesn't always do that. So, I
7 mean, there's some transparency there with
8 IFRA. So you can go read those in the
9 Journal of Food Science and Toxicology,
10 whatever it's called.

11 So, yeah, all those are
12 disclosed in the peer-reviewed literature. I
13 did review them where possible.

14 Q. You're not expressing an opinion
15 as to whether or not the chemical substances
16 that you identify in this section of your
17 report, 4.8, either cause or contribute to
18 ovarian cancer. Correct?

19 MS. O'DELL: Object to the form.

20 A. Actually, I am. I mean, I've
21 stated fairly clearly, I feel, that, you
22 know, you've got a whole bunch of irritants,
23 you've got a whole bunch of sensitizers, and
24 you've got a whole bunch of allergens that

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1 BY MR. ZELLERS:

2 Q. With respect to the chemicals
3 that are identified in this section of your
4 report dealing with the IFRA Category 5
5 restrictions, you have no information that
6 the amount of the chemical in baby powder or
7 Shower to Shower exceeded the IFRA
8 restrictions. Correct?

9 MS. O'DELL: Object to the form.

10 A. Isn't that the same question you
11 just asked?

12 BY MR. ZELLERS:

13 Q. Can you answer the question?
14 MS. O'DELL: He previously
15 answered the question. I'll object as
16 asked and answered. You may repeat
17 your answer, Dr. Crowley. You can
18 refer back and ask the court reporter
19 to repeat the answer, whichever you
20 prefer.

21 A. I think that -- I believe that
22 I've answered this close to 15 times today,
23 maybe -- maybe nearly 20.

24 I've not been provided with the

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1 quantitative composition of the Johnson &
2 Johnson fragrance mix in the baby powder or
3 Shower to Shower product. I can't make any
4 judgments to that without that, as I think
5 you well know.

6 BY MR. ZELLERS:

7 Q. In this section --

8 A. So I can't determine if the
9 Category 5 restrictions have been exceeded or
10 not without that information. Right?

11 Q. In the Category 5 restrictions,
12 dose or concentration would be important to
13 your analysis. Is that right?

14 MS. O'DELL: Objection to form.

15 A. So, for example, cinnamal has a
16 Category 5 restriction of 0.05 percent.

17 Since I don't know how much is present, I
18 can't make a judgment as to whether the
19 cinnamal present in baby powder exceeds
20 0.05 percent or not. There's a bunch of
21 other fragrance chemicals here too that have
22 these restrictions similar to Shower to
23 Shower. Let's save each other some time. I
24 can't make that judgment because your client

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1 FDA inactive ingredient list, it is likely to
2 contribute to the development of ovarian
3 cancer. Correct?

4 MS. O'DELL: Object to the form.

5 A. So I can't understand the
6 question because you've got two nots, so
7 maybe just ask me what my opinion is.

8 BY MR. ZELLERS:

9 Q. Well, you expressed your opinion
10 in your report. Is that right?

11 A. Yes.

12 Q. Is it your opinion that an
13 ingredient that's not listed on the FDA
14 inactive ingredient list is likely to
15 contribute to the development of ovarian
16 cancer?

17 A. You asked me if it's my opinion
18 that if it's absent from that IID it's likely
19 to cause ovarian cancer?

20 Q. Correct.

21 MS. O'DELL: Object to the form.

22 BY MR. ZELLERS:

23 Q. That's not your opinion, is it?

24 A. No.

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1 hasn't given me the information to be able to
2 do that.

3 BY MR. ZELLERS:

4 Q. In your report, Section 4.10,
5 you discuss the FDA inactive ingredient list.
6 Is that right?

7 A. Yes.

8 Q. The ingredients that you list
9 are only included if they are used in
10 FDA-approved drug products. Is that right?

11 A. That's correct.

12 Q. Most FDA-approved drug products
13 do not use fragrances. Is that right?

14 MS. O'DELL: Objection to the form.

15 A. You know, I don't know what
16 percentage use a fragrance. They're all
17 chemicals. Right? So they're inactive
18 ingredients, supposedly, right, or inert --
19 although, certainly not all of them, but many
20 of them have buffers, and film formers are
21 often used, too.

22 BY MR. ZELLERS:

23 Q. You're not expressing an opinion
24 that if an ingredient is not listed on the

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1 MR. ZELLERS: I have no further
2 questions. Thank you.

3 MR. FERGUSON: Why don't we go
4 off the record for a second, please.

5 MS. O'DELL: Yeah.

6 THE VIDEOGRAPHER: Going off the
7 record, the time is 5:04 p.m.

8 (Recess from 5:04 p.m. to
9 5:18 p.m.)

10 THE VIDEOGRAPHER: Back on the
11 record. The time is 5:18 p.m.

12 ---

13 EXAMINATION

14 ---

15 BY MR. FERGUSON:

16 Q. Dr. Crowley, my name is Ken
17 Ferguson, and along with Mr. Donath to my
18 right, I represent Imerys. Do you understand
19 that?

20 A. Yes.

21 Q. Do you know who Imerys is?

22 A. Yes.

23 Q. Tell me what your understanding
24 is.

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<p>1 A. It's a company that mines talc 2 and sells talc. 3 Q. So over the course of the day, 4 we've been discussing your opinions as 5 expressed in your testimony today and your 6 report relating to the fragrance chemicals 7 that you stated are included in Johnson's 8 baby powder and formerly Shower to Shower. 9 Correct? 10 A. Yes. 11 Q. And would you agree your 12 opinions in this case that you will express 13 in your testimony as well as your report only 14 relate to fragrance chemicals? 15 A. Yes, to a certain extent. 16 Q. All right. Well, I better ask 17 about that. What do you mean by "to a 18 certain extent"? 19 A. Yeah. So some of these 20 fragrance chemicals have been identified as 21 carcinogens, meaning if another material is 22 present that is carcinogenic, they promote 23 its carcinogenic activity. 24 Q. Well, let me put it this way.</p>	<p>Page 334</p> <p>1 flotation process as you described it, but 2 you ran out of time. Correct? 3 A. That's correct. 4 Q. And I think in your testimony, 5 the way you put it -- I just want to make 6 sure I understand -- you said you won't be 7 expressing an opinion on the flotation 8 process today. Is it fair there's nothing 9 about the flotation process in your report? 10 Correct? 11 A. That's correct. 12 Q. And in this case -- for purposes 13 of your testimony in this case, you don't 14 intend to address the flotation process. 15 Correct? 16 A. I suppose if I'm asked I'll 17 answer the questions based on what I did 18 review. 19 Q. Well, since it's not contained 20 in your report, I'm sure the attorneys would 21 not want us to ask you questions about it in 22 that sense, but let me -- well, let me put it 23 this way. 24 You did not complete your work</p>
<p>1 First of all, your -- the title of your 2 report says "Rule 26 Report of Michael M. 3 Crowley, Ph.D. Regarding the Fragrance 4 Chemical Constituents in Johnson & Johnson 5 Talcum Powder Products." Correct? 6 A. Yes. 7 Q. And you stand by that title for 8 your report. Correct? 9 A. Yes. 10 MS. O'DELL: Object to the form. 11 A. Yeah. 12 BY MR. FERGUSON: 13 Q. You have no opinions that relate 14 to the talc as it was supplied to Johnson & 15 Johnson Consumer Companies. Correct? 16 A. That's correct. 17 Q. So no opinions about the talc 18 before the fragrance chemicals were added. 19 Fair? 20 A. That's correct. 21 Q. Now, at one point in your 22 testimony earlier today, you said that you 23 had -- and I'm not sure exactly how you put 24 it. You were intending to look at the</p>	<p>Page 335</p> <p>1 that you were considering doing regarding the 2 flotation process. Correct? 3 A. That's correct. 4 Q. Because you ran out of time. 5 Correct? 6 A. Yes. 7 Q. And so your work with regard to 8 the flotation process as it relates to the 9 talc was not -- was not completed? 10 MS. O'DELL: Object to the form, 11 asked and answered. 12 A. Yeah, that's correct. 13 BY MR. FERGUSON: 14 Q. You indicated earlier that your 15 initial contact on -- regarding this case was 16 from Margaret Thompson. Correct? 17 A. Yes. 18 Q. Did you know Margaret Thompson 19 before you were contacted about working on 20 this case? 21 A. No. 22 Q. You talked about the fact that 23 you had read Dr. Thomas Dydek's report. 24 Correct?</p>

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1 A. Yes.
2 Q. Before you read Dr. Dydek's
3 report, were you acquainted with him at all?
4 A. No.
5 Q. Since you've read his report,
6 have you been -- have you met him? Have you
7 talked to him at all?
8 A. No.
9 Q. How about a Dr. Alan Campion who
10 is at The University of Texas, I believe? Do
11 you know Dr. Campion?
12 A. I have met Dr. Campion.
13 Q. Okay. Can you just tell me in
14 general what the circumstances were?
15 A. I met him when I was in graduate
16 school, and shockingly I ended up sitting
17 next to him on a plane on our way to a
18 conference about ten years ago.
19 Q. Have you had any discussions
20 with Dr. Campion regarding your work in this
21 matter?
22 A. No.
23 Q. Do you know whether or not he is
24 an expert witness who has been listed in this

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1 said, or would you like me to repeat myself?
2 A. I heard you okay, but it did get
3 muffled at a few points, so we should
4 probably take our time.
5 Q. Okay. Thank you, Dr. Crowley.
6 So what I said before is that I am Renee
7 Appel, and I represent Personal Care Products
8 Counsel, and I had a few follow-up questions
9 for you.
10 A. Okay.
11 Q. The CIR is not a federal agency.
12 Correct?
13 A. That's correct.
14 Q. So the CIR has no regulatory
15 authority. Correct?
16 A. That's correct.
17 MS. APPEL: Okay. That's it.
18 MR. ZELLERS: Anyone else?
19 MS. O'DELL: I have questions,
20 so --
21 MR. ZELLERS: Go ahead.
22 MS. O'DELL: Do you have an
23 objection to that?
24 MR. ZELLERS: Well -- no, I

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1 matter?
2 A. I believe he has.
3 MR. FERGUSON: I think that's
4 all I have. Thank you, Dr. Crowley.
5 THE WITNESS: You're welcome.
6 MR. ZELLERS: Apparently --
7 Ms. Appel, do you have some questions
8 or any questions?
9 MS. APPEL: Yes, please, very
10 briefly.
11 ---
12 EXAMINATION
13 ---

14 BY MS. APPEL:
15 Q. Hi, again, Dr. Crowley. Renee
16 Appel. I represent Personal Care Products
17 Counsel. I just had a few questions for you.
18 A. Okay.
19 Q. Can you hear me okay?
20 MS. O'DELL: Actually, we
21 couldn't hear that, so if you could
22 speak up, please. Thank you.
23 BY MS. APPEL:
24 Q. Did you hear anything I just

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1 don't have an objection.
2 MS. O'DELL: Did you expect -- I
3 was just wondering why you -- if
4 anybody else has questions. I'm going
5 to ask Dr. Crowley some questions,
6 but -- okay? All right. Great.
7 ---
8 EXAMINATION
9 ---

10 BY MS. O'DELL:
11 Q. Dr. Crowley, I have a few
12 questions I'd like to ask you just to clarify
13 some of your testimony from earlier today.
14 Let me just start at the
15 beginning and just ask for you to tell us a
16 little bit about your qualifications in terms
17 of chemicals and chemicals that are used in
18 fragrances, pharmaceuticals, other
19 flavorants.
20 A. Sure. I have a Bachelor's
21 degree in chemistry, a Master's degree in
22 organic chemistry. My Doctorate is in
23 molecular pharmaceutics. All three of those
24 disciplines deal with chemicals and their

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1 biological properties. I have worked with
2 flavors and fragrances throughout my career,
3 although the primary focus has been on drug
4 development. I have worked on the
5 development of foods, nutritional supplements
6 which are regulated as foods, and I've worked
7 on cosmetic products as well.

8 All of those chemicals that go
9 into those types of products are in fact
10 chemicals. Whether you call them a flavor or
11 a fragrance, they are chemicals.

12 Q. And in terms of -- of your
13 report, you reference in your report
14 fragrance chemicals, but by using that
15 terminology, what were you really referring
16 to?

17 A. Well, Johnson & Johnson calls
18 them fragrance chemicals, so I utilized their
19 term, but they're -- they're chemicals.

20 Q. And, in fact, are some of those
21 chemicals not actually, quote, fragrance
22 chemicals in the technical sense?

23 A. That's correct.

24 MR. ZELLERS: Objection; form.

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1 wasn't very hard because the government makes
2 those rules pretty clear, and the industry
3 trade groups like IFRA and CIR also, you
4 know, provide information to support the use
5 of those chemicals in an appropriate fashion.

6 THE REPORTER: In an appropriate
7 fashion?

8 THE WITNESS: Yes.

9 BY MS. O'DELL:

10 Q. Did you outline the results of
11 your review of the evidence in your report as
12 well as the appendices that's attached to
13 your report?

14 A. Yes.

15 Q. And you referred to data in your
16 appendices earlier today -- actually,
17 throughout your testimony. And would that
18 data include the information that is located
19 at the links that you provided in your
20 appendices?

21 A. Yes.

22 Q. So in addition to what's
23 actually listed in the appendices, the data
24 that is contained in the link that you

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1 A. That's correct, they aren't --
2 there are some that are clearly not
3 fragrances.

4 BY MS. O'DELL:

5 Q. And -- and what were you asked
6 to do in giving your opinions in this case?

7 A. So the two questions in my
8 report. You know, are the products in
9 compliance with established industry and
10 regulatory standards, the first question.
11 And the second question was what are the
12 properties of the fragrance chemicals, and do
13 they contribute to the inflammatory
14 properties, toxicity, and potential
15 carcinogenicity of the talcum powder
16 products.

17 So that included looking at the
18 physical and chemical properties, reviewing
19 all of the available literature, including
20 some literature that was only available via
21 purchase or access to proprietary databases.
22 Reviewing that, and then forming my opinion
23 based upon that.

24 The regulation portion of this

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1 included would also be material that you
2 reviewed and considered in reaching your
3 opinions?

4 A. Yes.

5 Q. Now, in reviewing the list of
6 chemicals or starting with that list of
7 chemicals, I mean -- let me just -- let me
8 back up and just strike that and start again.

9 Are fragrance formulas closely
10 held trade secrets?

11 MR. ZELLERS: Objection; form.

12 A. Yes, oftentimes they are.

13 BY MS. O'DELL:

14 Q. In the case of Johnson's baby
15 powder's fragrance, as well as Shower to
16 Shower's fragrance, is that -- the
17 information about the formula that you used
18 for those fragrances something that
19 necessarily would have to be provided by
20 Johnson & Johnson?

21 A. It would have been useful, but
22 it wasn't.

23 Q. In the data that you were
24 provided initially to undertake the work that

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1 you've done in this case was actually
2 provided through a pleading that was issued
3 by Johnson & Johnson in a state court case in
4 St. Louis. Correct?

5 A. Is that the Ingham --
6 MS. O'DELL: Yeah. Let me ask
7 if I can have some exhibit stickers,
8 please?

9 MR. ZELLERS: Oh, yes, exhibit
10 stickers. Yes.

11 MS. O'DELL: Thank you.
12 (Exhibit No. 32 marked)

13 BY MS. O'DELL:

14 Q. Let me show you what I'm marking
15 as Exhibit 32. Is this information that was
16 provided to you in order to learn the
17 chemicals that were included in both Shower
18 to Shower and Johnson's baby powder?

19 A. Yes.

20 Q. And if you'll turn to Page 2 of
21 the document, according to this answer to
22 Interrogatory 19, this is -- this list of
23 chemicals provided was the current fragrance
24 composition for Johnson's baby powder?

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1 Q. It was a bad question. Look at
2 Page 7, if you don't mind.
3 A. Okay.
4 Q. Was the information provided in
5 Exhibit 32 information that attorneys for
6 Johnson & Johnson provided to the plaintiffs
7 in that case?

8 MR. ZELLERS: Form and
9 foundation objection.

10 A. That's what it looks like. It
11 says, "Respectfully submitted" by the names
12 of three attorneys who are labeled as
13 attorneys for defendants Johnson & Johnson
14 and Johnson & Johnson Consumer Companies, now
15 known as Johnson & Johnson Consumer,
16 Incorporated.

17 BY MS. O'DELL:

18 Q. Was this the list of chemicals
19 that you utilized for the majority of the
20 time you were doing your evaluation of these
21 chemical components?

22 MR. ZELLERS: Objection; form.

23 A. Yes.

24

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1 A. That's correct.

2 Q. And this listing does not
3 include information about the concentration
4 of the particular chemicals in the baby
5 powder fragrance?

6 A. That's correct.

7 Q. And is that also true as it
8 relates to this answer to interrogatory
9 regarding Shower to Shower?

10 A. Yes.

11 Q. And is this information that was
12 provided to the plaintiffs and to the Court
13 in the Circuit Court of the City of St. Louis
14 by attorneys for Johnson & Johnson and
15 Johnson & Johnson Consumer, Inc.?

16 MR. ZELLERS: Objection; form,
17 foundation.

18 BY MS. O'DELL:

19 Q. Well, I'll just ask you -- I'll
20 address the objection. If you'll look at
21 Page --

22 A. I don't understand the question.

23 Q. Well, let me ask it again.

24 A. Okay.

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1 BY MS. O'DELL:

2 Q. And shortly prior to the
3 disclosure of your report, did you receive
4 another list of fragrance ingredients for
5 both baby powder and Shower to Shower?

6 A. I don't know if I'd call it
7 another list. I received a second list.
8 Yeah, I guess another list.

9 Q. Yeah. Fair, it's hard to know
10 how to characterize it. But I'll represent
11 to you --

12 (Exhibit No. 33 marked)

13 BY MS. O'DELL:

14 Q. This is Exhibit 33. This is a
15 list of chemicals that were provided by
16 Johnson & Johnson's lawyer, Mr. Wyatt's
17 partner, Richard Bernardo, after plaintiffs,
18 in the multi-district litigation, had asked
19 for the formula itself, including the
20 concentration of chemicals.

21 This -- would you just describe
22 for the jury and the Judge, certainly, what
23 this -- the information in this list contains
24 or this exhibit contains for the chemicals in

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<p>1 Johnson's baby powder?</p> <p>2 A. Okay. So there's -- there's 3 four columns. The first column is a 4 description of the fragrance chemical. The 5 second column is labeled "minimum," the third 6 column is labeled "maximum," and the fourth 7 column is the CAS number that we spoke about 8 earlier today.</p> <p>9 Q. And are there units that have 10 been supplied in order to understand what the 11 minimum and maximum amount --</p> <p>12 A. No. You don't know whether 13 that's parts per million, percent, 14 milligrams, micrograms, femtograms, or some 15 other unit of measure.</p> <p>16 Q. Would that information be 17 critical in order to understand the 18 concentrations of the specific chemicals in 19 the fragrance?</p> <p>20 A. Yes, along with other pieces of 21 information, too. That would be one -- one 22 important part of doing that analysis.</p> <p>23 Q. And is that information that 24 could only be provided by Johnson & Johnson,</p>	<p>Page 350</p> <p>1 insufficient to understand the concentrations 2 or other relevant facts about the chemicals?</p> <p>3 A. Yes. 4 (Exhibit No. 35 marked)</p> <p>5 BY MS. O'DELL:</p> <p>6 Q. Okay. Now, I want to show you 7 one last document -- and I'm marking that as 8 Exhibit 35 -- and ask you to identify that.</p> <p>9 A. Exhibit 35 is titled "Changes to 10 Johnson & Johnson's Baby Powder Fragrance 11 Ingredients."</p> <p>12 Q. Did you take into consideration 13 these historical changes in the baby powder 14 formulation when you reached your opinions in 15 this case?</p> <p>16 A. Yes. I mean, I only had -- I 17 think I had them for three days before the 18 report was due, so it was kind of rushed. 19 But what I saw was that from 2008 to 2014, 20 there were only minimal changes, and even 21 with this information, it didn't look like 22 there was any substantial change other than 23 styrene was changed styrax oil. You know, 24 Galaxolide 50 DEP I presumed to mean that it</p>
<p>Page 351</p> <p>1 who is essentially the owner of the 2 fragrance?</p> <p>3 MR. ZELLERS: Form, objection.</p> <p>4 A. I suppose so. 5 (Exhibit No. 34 marked)</p> <p>6 BY MS. O'DELL:</p> <p>7 Q. I want to show you what I've 8 marked as Exhibit 34. This is a listing of 9 chemicals very similar to Exhibit 34. And 10 just to make sure I didn't misstate that, 11 this is Exhibit 35 that I handed to you. Is 12 that a list of chemicals --</p> <p>13 A. It's Exhibit 34.</p> <p>14 Q. Is it?</p> <p>15 A. The first one was 33, and this 16 one is 34.</p> <p>17 Q. All right. Thank you. Is 18 Exhibit 34 a similar list of chemicals 19 that -- for Shower to Shower?</p> <p>20 A. Yes.</p> <p>21 Q. And does it provide essentially 22 the same information?</p> <p>23 A. Yes.</p> <p>24 Q. And is that information also</p>	<p>Page 353</p> <p>1 was the Galaxolide dissolved at a 50 percent 2 level in diethyl phthalate, and that it was 3 replaced by Galaxolide 50 BB. I didn't know 4 what BB was, but I presumed it was a 5 different solvent than diethyl phthalate.</p> <p>6 So even with this information, 7 there was not a whole lot that I could 8 ascertain from it, but it didn't change my 9 opinions.</p> <p>10 Q. And certainly the schedule in 11 producing your report was intense, but did 12 you have sufficient time to do what was 13 necessary to render your opinions in this 14 case?</p> <p>15 A. Yes, I did. I mean, more time 16 would have been nice, but I was able to get 17 the information that I needed to form my 18 opinions and had more than sufficient 19 information on which to base them.</p> <p>20 I did want to make one last 21 comment about Exhibit 35.</p> <p>22 Q. Go ahead.</p> <p>23 A. It looks like styrene --</p> <p>24 MR. ZELLERS: Objection.</p>

<p>1 BY MS. O'DELL:</p> <p>2 Q. If you have comments about</p> <p>3 Exhibit 35, please share them with us.</p> <p>4 A. Yeah. It looks like styrene was</p> <p>5 removed from the formula twice, about a week</p> <p>6 apart. So it got removed on April 8th of</p> <p>7 2014, and then it got removed again on</p> <p>8 April 17th. So I didn't know if that meant</p> <p>9 that the amount was just reduced or if it was</p> <p>10 completely replaced, and the information</p> <p>11 really is insufficient to make that judgment.</p> <p>12 Q. You were asked a number of</p> <p>13 questions today regarding dose, the amount of</p> <p>14 a particular concentration of a chemical, and</p> <p>15 the impact of a dose of that chemical in your</p> <p>16 analyses.</p> <p>17 Is -- is information regarding</p> <p>18 dose essential for your opinions in this</p> <p>19 case?</p> <p>20 A. No.</p> <p>21 Q. Why?</p> <p>22 A. Well, as I said a bunch of</p> <p>23 times, I was not provided the information to</p> <p>24 be able to ascertain a dose. Even more</p>	<p>1 chemicals. Right? So very likely there's</p> <p>2 additive effects.</p> <p>3 And then I talked about the fact</p> <p>4 that the fragrance chemicals have film</p> <p>5 formers like rosin and Chem 4 present and</p> <p>6 that they will help adhere the fragrance</p> <p>7 chemical to the talc product.</p> <p>8 The rosin was used as a</p> <p>9 sustained release matrix in the</p> <p>10 pharmaceutical world to make extended release</p> <p>11 tablets. It's also being used as a film</p> <p>12 coating to delay the release of drugs. So</p> <p>13 that fragrance chemical is going to go with</p> <p>14 that talc particle wherever it may land, and</p> <p>15 it's also going to sustain the exposure of</p> <p>16 the fragrance chemical that may be attached</p> <p>17 to it.</p> <p>18 And lastly, you know, I was also</p> <p>19 asked about the routine, you know -- the</p> <p>20 exposure, you know, and could I determine,</p> <p>21 you know, how much was, you know, applied.</p> <p>22 Typical tox studies and safety studies are</p> <p>23 short term. They might be multi-day,</p> <p>24 sometimes up to a couple of weeks or a month.</p>
<p>1 importantly, the safety studies are absent</p> <p>2 for vaginal administration. So it's not</p> <p>3 just, you know, give a certain amount to, you</p> <p>4 know, the skin or the vaginal area. You do</p> <p>5 safety studies in animals for the intended</p> <p>6 route of administration.</p> <p>7 In addition, content uniformity</p> <p>8 studies on the fragrance haven't been</p> <p>9 provided. We asked for those as well. In</p> <p>10 other words, if you're adding, you know,</p> <p>11 0.5 -- 0.05 percent styrene to the talc and</p> <p>12 you make 1,000 kilos of baby powder and you</p> <p>13 sample the top, middle, and bottom, left,</p> <p>14 right, and middle, and you draw a sample and</p> <p>15 measure the uniformity and homogeneity of the</p> <p>16 baby powder or Shower to Shower, is that</p> <p>17 fragrance chemical present in a uniform</p> <p>18 manner in each?</p> <p>19 Another consideration is, you</p> <p>20 know, the safety studies are usually single</p> <p>21 ingredient safety studies. So, you know, if</p> <p>22 we were to do a safety study of para-Cresol</p> <p>23 in an animal, it would be simply that. It</p> <p>24 wouldn't be para-Cresol and another 142 other</p>	<p>1 The FDA has recently published guidances that</p> <p>2 request safety studies in accord with the</p> <p>3 frequency of administration -- short term,</p> <p>4 intermediate and long term. And for chronic</p> <p>5 administration, the expectation is that</p> <p>6 they'll do two years.</p> <p>7 So there have been repeated</p> <p>8 doses, repeated exposures, and thousands of</p> <p>9 applications.</p> <p>10 And lastly, in this matter, baby</p> <p>11 powder is directed to infants. Shower to</p> <p>12 Shower is directed towards women. We have</p> <p>13 two very different anatomies and physiologies</p> <p>14 in terms of most babies are a little bit</p> <p>15 smaller than adult women. So all those</p> <p>16 considerations need to be taken into -- into</p> <p>17 consideration.</p> <p>18 Lastly, you know, the question</p> <p>19 about dose is immaterial with genotoxic</p> <p>20 materials. As I said earlier, a genotoxic</p> <p>21 material, there is no threshold for it. A</p> <p>22 single molecule is sufficient to cause harm.</p> <p>23 Q. You were asked a series of</p> <p>24 questions about styrene, and the suggestion</p>

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1 was made by counsel for J&J that styrene has 2 not been determined to be harmful in humans. 3 Do you recall that line of questions? 4 A. Yes. 5 Q. You know, has -- what's the 6 current IARC classification for styrene? 7 A. It was recently updated. I 8 think it's now a 2A. 9 Q. And what's a 2A? 10 A. IARC 2A is probably carcinogenic 11 to humans. It means limited evidence of 12 carcinogenicity in humans and sufficient 13 evidence of carcinogenicity in animal studies 14 or inadequate evidence of carcinogenicity in 15 humans and sufficient evidence of 16 carcinogenicity in animals, and strong 17 evidence that the carcinogen is meted by a 18 mechanism that does operate in humans. 19 Q. Has the National Toxicology 20 Program evaluated styrene? 21 A. Yes. 22 Q. And what was their determination 23 in terms of its potential ability to cause 24 cancer?	Page 358 1 which is GHS. Do you recall that? 2 A. Yes. 3 Q. Is that a commercial database 4 that requires some type of payment in order 5 to be able to obtain all the information? 6 A. I believe so. 7 Q. And that's not information that 8 you had access to. Correct? 9 A. No. I just -- I looked at that 10 work that was in the public domain. 11 Q. And is the information in the 12 public domain that you had available to you 13 the MSDS sheets that were produced by the 14 manufacturers of those substances? 15 A. Yes. 16 Q. And so to the degree that J&J's 17 counsel suggested that somehow you had access 18 to that database, that's not correct? 19 A. That's correct. 20 Q. And that would be something, 21 typically, that would be available only to 22 manufacturers? 23 MR. ZELLERS: Objection; form, 24 foundation.
1 MR. ZELLERS: Objection; form, 2 foundation. 3 BY MS. O'DELL: 4 Q. I'll restate the question. What 5 was the National Toxicology's 6 determination -- Program's determination 7 regarding styrene? 8 A. I'm on Page -- Page -- are you 9 talking about IARC or NTP? 10 Q. NTP. Sorry. 11 A. Sorry. I'm going to have to 12 pull up that. 13 Q. Let me just ask you this 14 question and see if it -- has styrene been 15 determined by NTP to reasonably -- as 16 reasonably anticipated to be a human 17 carcinogen? 18 A. Yes. 19 MR. ZELLERS: Form, foundation, 20 objection. 21 BY MS. O'DELL: 22 Q. You were asked questions, also, 23 in the last segment of J&J's examination 24 about a database that is -- the acronym for	Page 359 1 A. That's correct, it would be 2 available to those that want to pay for it. 3 BY MS. O'DELL: 4 Q. You were asked questions 5 about -- I believe you referenced this 6 earlier in your testimony, and you used the 7 term "co-carcinogen." What's a 8 co-carcinogen? 9 A. A co-carcinogen is a chemical 10 that by itself may not be carcinogenic, but 11 when administered in the presence of a 12 carcinogen, it increases the carcinogen's 13 activity. 14 Q. Were you asked to do an exposure 15 assessment for any individual plaintiffs? 16 A. No. 17 Q. Were you asked to do any type of 18 an exposure analysis generally? 19 A. No. 20 Q. And as I believe you've 21 testified, that wasn't necessarily -- 22 necessary for the opinions you've rendered in 23 this case? 24 A. No.

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1 Q. Do your opinions in this case
2 include those that you've expressed in your
3 report as well as your deposition here today?

4 A. Yes.

5 Q. Do you hold those opinions to a
6 reasonable degree of scientific certainty?

7 A. I believe so, yes.

8 Q. In reaching those opinions, have
9 you used the methodology that's generally
10 accepted in your field as a chemist?

11 A. Yes.

12 Q. And have you used the same rigor
13 and attention to detail in this exercise in
14 your work in this case as you use in your
15 practice in consulting and formulating drugs
16 and other compounds?

17 A. Yes.

18 Q. You were asked questions by
19 Imerys' counsel regarding the flotation
20 process and the chemicals involved in the
21 flotation process. Would it be fair to say
22 that your work is ongoing in relation to that
23 question?

24 A. Yes.

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1 anything further at the moment,
2 Dr. Crowley.
3 - - -

4 FURTHER EXAMINATION
5 - - -

6 BY MR. ZELLERS:

7 Q. Dr. Crowley, are you aware of
8 any study that establishes styrene exposure
9 as a cause or a contributing cause to ovarian
10 cancer in humans?

11 MS. O'DELL: Objection; asked
12 and answered.

13 A. Yeah, so as we've talked about,
14 those studies are unethical, and that's why
15 there aren't any.

16 MR. ZELLERS: I have no further
17 questions. I do just want to put a
18 notation on the record that at the
19 start of the deposition we received
20 this update. It's Exhibit -- we've
21 marked it as Exhibit 3. I have not had
22 a chance to look at it. It's possible
23 that I may have some questions relating
24 to Exhibit 3, once I do have a chance

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1 MR. FERGUSON: Object to form.
2 THE REPORTER: Who was the
3 objection?

4 MR. FERGUSON: Sorry.

5 THE REPORTER: Thank you.

6 BY MS. O'DELL:

7 Q. You were -- you cite in your
8 report the CIR analyses of certain chemicals,
9 to the degree they were available. Why did
10 you include CIR as a part of the data you
11 reported?

12 MR. ZELLERS: Objection; form.

13 A. They're an industry trade group
14 that examines the safety of cosmetic
15 ingredients, and Johnson & Johnson is a
16 member.

17 BY MS. O'DELL:

18 Q. Do you -- excuse me. Sorry.

19 A. And they're expected to follow
20 CIR rules.

21 Q. Do you consider the CIR
22 authoritative?

23 A. No.

24 MS. O'DELL: I don't have

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1 to look at it and study. I just want
2 to put that notation on the record.
3 I'm not asking for an agreement.

4 MS. O'DELL: Well, no agreement.
5 This is your opportunity. I think,
6 Counsel, you have time available to you
7 if you want to take a break and look at
8 it. It's a six-page document. It's
9 very straightforward, and you're
10 welcome to ask Dr. Crowley questions,
11 but he's -- he's here today to answer
12 them.

13 MR. ZELLERS: It's a nine-page
14 document. It's very technical in
15 nature. I am not capable to sit here
16 on the fly and to go through and review
17 and analyze this document and this
18 material.

19 It may be that I have no further
20 questions relating to this document,
21 but the Doctor indicated that he had
22 completed this document on December
23 18th. It was not produced to the
24 defendants until today, right when we

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1 walked into the deposition.

2 So I'm just making a note that I
3 do want to go look at it, and at least
4 reserving the opportunity to raise it
5 with the Court if we feel we need time
6 to ask questions about it.

7 The other thing that I will ask
8 is that -- I'll request that you update
9 Deposition Exhibit 2, which are the
10 invoices, with whatever invoices have
11 been submitted by Dr. Crowley that have
12 not been produced here today.

13 MS. O'DELL: Let me just respond
14 to that, because I've checked our
15 files. We don't have another invoice.
16 To the degree that there's an invoice
17 in the future, which I'm sure there
18 will be, obviously we'll give that to
19 you, but it's not deficient as we stand
20 here today. Just to point that out.

21
22
23
24

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1 Johnson's counsel? And it's the --

2 A. I don't know if I still have it.

3 Hang on.

4 Q. I'll be happy to provide you my
5 copy.

6 A. Okay.

7 Q. Would you explain what Exhibit 3
8 is?

9 A. Exhibit 3 is a comparison of the
10 chemical abstract numbers that I found based
11 upon the information that was provided to me
12 at the outset of my work on this matter with
13 those disclosed in the Exhibits 33 and 34 by
14 J&J. Out of 175 chemicals, I think we had
15 different CAS numbers for 11, and it turns
16 out that some of the CAS numbers provided by
17 J&J are effectively the same as mine, just
18 multiple numbers for the same chemical.

19 For example, the first item was
20 Boswellia carterii oil. We have two
21 different CAS numbers. When I searched what
22 the J&J CAS number was, I found that it -- it
23 says that that number refers to Boswell --
24 Boswellia carterii resin. The CAS number I

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1 ---
2 FURTHER EXAMINATION
3 ---

4 BY MR. FERGUSON:

5 Q. I have what I hope is just one
6 question, which is: With regard to the
7 question you just answered that Ms. O'Dell
8 asked you regarding the flotation process and
9 your answer that your work is ongoing, I just
10 want to make clear, in your 200-page or so
11 report, there's not one word about anything
12 relating to the flotation process that you
13 evaluated. Correct?

14 A. That's correct.

15 MR. FERGUSON: That's all.

16 MS. O'DELL: I have one last
17 question.
18 ---

19 FURTHER EXAMINATION
20 ---

21 BY MS. O'DELL:

22 Q. Dr. Crowley, can you turn to
23 Exhibit 3, because I want to try to address
24 the issue that's been raised by Johnson &

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1 found was for Boswellia carterii oil,
2 according to PubChem and the FDA website.
3 I also checked fragrance
4 companies and verified that. So in this
5 case, it didn't represent any changes in my
6 report.

7 Some of the CAS numbers that
8 were provided by J&J are clearly wrong.
9 They're -- I think there are some errors
10 there. For example, for Cedrus Atlantic
11 cedarwood bark oil -- I'm sorry. That's not
12 the one I was thinking of.

13 Well, copper chlorophyll. The
14 J&J CAS number does not correspond to copper
15 chlorophyll under any of the search engines
16 that I looked at.

17 The J&J CAS number provided for
18 gamma-Undecalactone does not correspond to
19 that chemical. It's peppermint oil, so I
20 think that that's a typo or mistake either in
21 the name or the CAS number.

22 Q. And so --

23 A. That's what the document is.
24 It's a comparison of the CAS numbers in

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<p>1 Exhibits 33 and 34 to those that are in my 2 report. 3 Q. Earlier in the deposition, J&J's 4 counsel suggested that -- that you 5 plagiarized some of the general definitions 6 that were contained in your report. Do you 7 recall that line of questioning? 8 A. Yes. 9 Q. Any of that information that 10 J&J's counsel showed you today, did that 11 change your opinions? 12 A. No. 13 Q. Have any impact on your 14 opinions? 15 A. No. 16 Q. Were they anything more than 17 general definitions? 18 MR. ZELLERS: Objection; form, 19 foundation. 20 A. Just foundational information, 21 you know, background information. I thought 22 I got the definition of an irritant or a 23 sensitizer from a medical dictionary. The 24 fact that it's evidently word for word from</p>	<p>Page 370</p> <p>1 CERTIFICATE 2 3 4 5 I HEREBY CERTIFY that the 6 witness was duly sworn by me and that the 7 deposition is a true record of the testimony 8 given by the witness. 9 It was requested before 10 completion of the deposition that the 11 witness, MICHAEL CROWLEY, Ph.D., have the 12 opportunity to read and sign the deposition 13 transcript. 14 15 16 STEVEN STOGEL 17 Certified LiveNote Reporter 18 Certified Shorthand Reporter 19 CSR No. 6174-Expires 12/31/20 20 Dated: January 7, 2019 21 22 (The foregoing certification 23 of this transcript does not apply to any 24 reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.) 25</p>
<p>1 Wikipedia is really immaterial to how I 2 formed my opinion. 3 MS. O'DELL: No further 4 questions. 5 MR. ZELLERS: No further 6 questions. Thank you. 7 MR. FERGUSON: Nothing further. 8 MS. O'DELL: Thank you. 9 THE VIDEOGRAPHER: This 10 concludes the deposition of Dr. Michael 11 Crowley. Going off the record, the 12 time is 5:59 p.m. 13 (Deposition concluded at 14 5:59 p.m.) 15 16 17 18 19 20 21 22 23 24</p>	<p>Page 371</p> <p>1 INSTRUCTIONS TO WITNESS 2 3 Please read your deposition 4 over carefully and make any necessary 5 corrections. You should state the reason in 6 the appropriate space on the errata sheet for 7 any corrections that are made. 8 After doing so, please sign 9 the errata sheet and date it. 10 You are signing same subject 11 to the changes you have noted on the errata 12 sheet, which will be attached to your 13 deposition. 14 It is imperative that you 15 return the original errata sheet to the 16 deposing attorney within thirty (30) days of 17 receipt of the deposition transcript by you. 18 If you fail to do so, the deposition 19 transcript may be deemed to be accurate and 20 may be used in court. 21 22 23 24</p>

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<p>1 ----- 2 ER R A T A 3 ----- 4 PAGE LINE CHANGE 5 _____ 6 REASON: _____ 7 _____ 8 REASON: _____ 9 _____ 10 REASON: _____ 11 _____ 12 REASON: _____ 13 _____ 14 REASON: _____ 15 _____ 16 REASON: _____ 17 _____ 18 REASON: _____ 19 _____ 20 REASON: _____ 21 _____ 22 REASON: _____ 23 _____ 24 REASON: _____</p>	<p>Page 374</p> <p>1 LAWYER'S NOTES 2 PAGE LINE 3 _____ 4 _____ 5 _____ 6 _____ 7 _____ 8 _____ 9 _____ 10 _____ 11 _____ 12 _____ 13 _____ 14 _____ 15 _____ 16 _____ 17 _____ 18 _____ 19 _____ 20 _____ 21 _____ 22 _____ 23 _____ 24 _____</p> <p>Page 376</p>
<p>1 2 ACKNOWLEDGMENT OF DEPONENT 3 4 I, _____, do 5 hereby certify that I have read the foregoing 6 pages, 1 - 376, and that the same is a 7 correct transcription of the answers given by 8 me to the questions therein propounded, 9 except for the corrections or changes in form 10 or substance, if any, noted in the attached 11 Errata Sheet. 12 13 14 15 MICHAEL CROWLEY, Ph.D. DATE 16 17 18 Subscribed and sworn 19 to before me this 20 ____ day of _____, 20_____. 21 My commission expires: _____ 22 _____ 23 Notary Public 24 _____</p>	<p>Page 375</p>